

Cohere Medical Policy – Guidelines for Other Specialties

Clinical Guidelines for Medical Necessity Review

Consolidated Reference • 61 Policies

Updated on 05/26/2026

Guidelines for Other Specialties – Consolidated Edition

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Important Notices

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Cohere Medical Policy – Level of Care Criteria for Inpatient vs. Outpatient Services

Clinical Policy for Medical Necessity Review

Version: 3

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Policy Information:

Specialty Area: All Specialties

Policy Name: Cohere Medical Policy - Level of Care Criteria for Inpatient vs. Outpatient Services

Policy Number: CHP-212-3

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Level of Care Criteria for Inpatient vs. Outpatient Services

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Description

This policy is intended to aid in determining the appropriate level of care (inpatient vs. outpatient) for elective scheduled surgical or interventional procedures. In the absence of explicit indications in the Cohere Health medical policy, medical necessity will be determined using established clinical best practices as supported by peer-reviewed evidence, professional society guidelines, and state or national recommendations, unless directed by the health plan, and with additional consideration of patient-specific factors, including age, comorbidities, and social support, as well as procedural complexity and anticipated complications.

Medical Necessity Criteria

Indications

Inpatient care is considered appropriate if **ANY** of the following is **TRUE**:

- The surgical or interventional procedure involves **ANY** of the following:
 - Cardiovascular procedure and **ANY** of the following:
 - On the Medicare inpatient only (IPO) list; **OR**
 - Performed in conjunction with a procedure on the Medicare IPO list; **OR**
 - Not low risk, with sufficient complexity or duration indicating the need for close postoperative monitoring (e.g., tikosyn-loading)¹; **OR**
 - Surgical blood loss that is expected to require a transfusion²; **OR**
 - Post-operative wound care that is expected to be extraordinarily complex (e.g., complex drain management, pre-existing tissue damage due to injury, radiation, previous surgery, impaired circulation, sustained pressure, etc), with documentation of necessity and complexity⁴; **OR**
- The patient is considered pediatric and **ANY** of the following⁵⁻⁷:
 - The patient is medically complex as reflected in the medical record; **OR**
 - The surgery is considered high risk as defined by **ANY** of the following:
 - Surgical blood loss that is expected to require a transfusion; **OR**
 - Duration of anesthesia longer than 2 hours; **OR**
- American Society of Anesthesiologists (ASA) Physical Status Classification System ASA IV or higher in adult patients^{8,9}; **OR**
- Clinical comorbidities, including **ANY** of the following:
 - Cardiovascular disease, including **ANY** of the following^{10,11}:

- History of myocardial infarction (MI) within 90 days of the planned surgical procedure; **OR**
- Coronary artery disease (CAD) with ongoing cardiac ischemia requiring medical management and poor functional capacity (less than 4 METS or Canadian Cardiovascular Society [CCS] Class III or IV angina); **OR**
- Uncompensated chronic heart failure NYHA Class III or higher; **OR**
- Severe symptomatic valvular heart disease (VHD)¹²; **OR**
- Hepatic or renal compromise, including **ANY** of the following¹³:
 - Advanced liver disease with model for end-stage liver disease (MELD) score greater than 8; **OR**
 - End-stage renal disease with hyperkalemia, defined as a serum potassium level greater than 5; **OR**
 - On scheduled peritoneal dialysis or hemodialysis; **OR**
- Poorly controlled diabetes mellitus including **ALL** of the following:
 - Hemoglobin A1c greater than 8 in the 3 months prior to the planned surgical procedure; **AND**
 - **ANY** of the following¹⁴⁻¹⁶:
 - Documented history of frequent large fluctuations in blood glucose concentration (brittle diabetes) with clear documentation in the medical record of the need for inpatient management¹⁷; **OR**
 - Receives enteral or parenteral nutrition; **OR**
- Respiratory conditions, including **ANY** of the following:
 - Poorly controlled asthma (FEV1 less than 80%) despite appropriate medical management¹⁸; **OR**
 - Severe chronic obstructive pulmonary disease (COPD) symptomatic despite management or FEV1 less than 50%^{19,20}; **OR**
- Hematologic conditions, including thrombocytopenia with a recent platelet count less than 100,000/microL²¹; **OR**
- Neurological or neuromuscular conditions, including **ANY** of the following^{22,23}:
 - History of cerebrovascular accident (CVA) within 6 months of planned surgical procedure; **OR**
 - Recent stroke or transient ischemic attack (TIA) within 90 days of planned surgical procedure; **OR**

- Multiple sclerosis (MS) with acute symptom worsening or documented increased perioperative risk²⁴; **OR**
- Amyotrophic lateral sclerosis (ALS); **OR**
- Muscular dystrophy; **OR**
- Myelopathy with impact to activities of daily living (ADL), or fall risk clearly documented; **OR**
- Chronic, prescription high-dose opioid use with documented concern for post-operative pain management^{25,26}; **OR**
- Body mass index (BMI) greater than 40 with obstructive sleep apnea or documentation of additional medical complexities necessitating inpatient care²⁷⁻²⁹; **OR**
- The patient has documented evidence, including objective screening, of severe dementia³⁰⁻³²; **OR**
- The patient has severe deconditioning or is high risk for fall with clear documentation in the medical record; **OR**
- Pregnant or within 6 weeks post-partum and has a documented pregnancy-related risk factor necessitating inpatient care (e.g., increased risk of aspiration, thromboembolism, or need for maternal or fetal monitoring).^{33,34}

Medical Evidence

Determination of the appropriate level of care for elective surgical services involves consideration of several patient- and procedure-specific factors. The American Society of Anesthesiologists (ASA) Physical Status Classification System is a widely used preoperative evaluation tool, and has been successfully used in adult patients for over 60 years.⁸ A patient's physical status may be determined at several time points prior to the procedure, with the final assessment occurring on the day of surgery. Ferrari et al. (2021) identified that this system is not reliable for use in pediatric patients, notably in the presence of acute illness, and in determining how well a chronic condition was controlled; therefore, the ASA criteria should be reserved for adults.⁵

Bhat et al. (2024) reviewed perioperative management in patients with neuromuscular disorders. The authors note that these patients may be particularly vulnerable to postoperative complications, including aspiration and respiratory compromise, pneumonia, sepsis, and bleeding.²³ Recommendations for postoperative care included postural positioning to mitigate potential respiratory complications, consideration of specific metabolic factors that may be further exacerbated by blood loss and fluid replacement therapy, secretion management in patients unable to self-manage secretions, mitigation of extubation failure risks, and consideration of complications and adverse effects from pain and nausea control medications. These and other potentially serious postoperative complications led the authors to conclude that specific and detailed postoperative plans should be developed and implemented for all patients with neuromuscular disorders.

Hedge et al. (2017) reviewed ischemic heart disease and associated risk factors in elective surgery patients. They found that these patients are prone to myocardial infarction and arrhythmias during surgery; therefore, a thorough preoperative evaluation is needed, and any modifiable risk factors should be corrected prior to surgery.¹¹

Sethuraman et al. (2022) provided a narrative review of studies of hemoglobin A1c (HbA1c) levels within 8–12 weeks of surgery. While there is no consensus, they suggested HgbA1c levels should be checked prior to elective surgery and recommend a cut-off level of HgbA1c less than 8, with consideration of a lower cut-off of less than 7 for spine and joint replacement surgeries and cardiac surgeries.¹⁴

Madsen et al. (2023) discuss the additional risks associated with surgery in obese patients. These include longer operative times with higher adjusted odds of developing infection, venous thromboembolism, and renal complications.²⁸

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Policy Revision History/Information

Original Date: July 30, 2024		
Review History		
Version 2	08/28/2025	Annual review. Policy title changed. Formerly "Site of Service Criteria for Inpatient vs. Outpatient Services". Added indications for procedures on the Medicare IPO list, done in conjunction with such a procedure, and procedures not considered low risk. Added indications for procedures or patients with high probability of complex wound care, advanced dementia, pregnancy, and post-partum. Refined and clarified criteria for ASA physical classification, diabetes, MS, addiction, high BMI. Removed criteria for cardiac arrhythmia, hypertension, obstructive sleep apnea, bleeding disorders, sickle cell disease, oxygen dependence. Reorganized criteria for clarity and ease-of-use. Added description section. References added and updated throughout. Literature review - Medical Evidence section updated (Bhat et al., 2024).
Version 3	05/07/2026	Revision.

		Specified that indication for procedures on the Medicare IPO list applies only to cardiovascular procedures. Added myelopathy with impact on ADL or fall risk to neurological/neuromuscular conditions indications. Added specification that chronic high-dose opioid use requires documented concern for post-operative pain management. Added indication for severe deconditioning or high risk for fall. References reviewed.



Cohere Medical Policy – Level of Care Criteria for Inpatient vs. Outpatient Services

Clinical Policy for Medical Necessity Review

Version: 2

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Policy Information:

Specialty Area: All Specialities

Policy Name: Level of Care Criteria

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Level of Care Criteria

Description

This policy is intended to aid in determining the appropriate level of care (inpatient vs outpatient) for elective scheduled surgical or interventional procedures. In the absence of explicit indications in the Cohere Health medical policy, medical necessity will be determined using established clinical best practices as supported by peer-reviewed evidence, professional society guidelines, and state or national recommendations, unless directed by the health plan, and with additional consideration of patient-specific factors, including age, comorbidities, and social support, as well as procedural complexity and anticipated complications.

Medical Necessity Criteria

Indications

Inpatient care is considered appropriate if **ANY** of the following is **TRUE**:

- The surgical or interventional procedure involves **ANY** of the following:
 - The procedure is on the medicare inpatient only (IPO) list; **OR**
 - The procedure is being done in conjunction with a procedure on the medicare IPO list; **OR**
 - The procedure is not low risk, with sufficient complexity or duration indicating the need for close postoperative monitoring(e.g., tikosyn-loading)¹; **OR**
 - Surgical blood loss that is expected to require a transfusion²;
 - Post-operative wound care is expected to be extraordinarily complex (e.g., complex drain management, pre-existing tissue damage due to injury, radiation, previous surgery, impaired circulation, sustained pressure, etc), with documentation of necessity and complexity⁴; **OR**
- The patient is considered pediatric and **ANY** of the following⁵⁻⁷:
 - The patient is medically complex as reflected in the medical record; **OR**
 - The surgery is considered high risk as defined by **ANY** of the following:

- Expected blood loss that could require a transfusion; **OR**
 - Duration of anesthesia longer than 2 hours; **OR**
- American Society of Anesthesiologists (ASA) Physical Status Classification System ASA IV or higher in adult patients^{8,9}; **OR**
- Clinical comorbidities, including **ANY** of the following:
 - Cardiovascular disease, including **ANY** of the following^{10,11}:
 - History of myocardial infarction (MI) within 90 days of the planned surgical procedure; **OR**
 - Coronary artery disease (CAD) with ongoing cardiac ischemia requiring medical management and poor functional capacity (less than 4 METS or Canadian Cardiovascular Society (CCS) Class III or IV angina; **OR**
 - Uncompensated chronic heart failure NYHA Class III or higher; **OR**
 - Severe symptomatic valvular heart disease (VHD)¹²; **OR**
 - Hepatic or renal compromise, including **ANY** of the following¹³:
 - Advanced liver disease with model for end-stage liver disease (MELD) score greater than 8; **OR**
 - End-stage renal disease with hyperkalemia, defined as a serum potassium level greater than 5; **OR**
 - The patient is on scheduled peritoneal dialysis or hemodialysis; **OR**
 - The patient has poorly controlled diabetes mellitus (hemoglobin A1C greater than 8 in the 3 months prior to the planned surgical procedure) and **ANY** of the following¹⁴⁻¹⁶:
 - The patient has a documented history of frequent large fluctuations in blood glucose concentration (brittle diabetes) with clear documentation in the medical record of the need for inpatient management¹⁷; **OR**
 - The patient receives enteral or parenteral nutrition; **OR**
 - Respiratory conditions, including **ANY** of the following:
 - Poorly controlled asthma (FEV1 less than 80%) despite appropriate medical management¹⁸; **OR**
 - Severe chronic obstructive pulmonary disease (COPD) symptomatic despite management or FEV1 less than 50%^{19,20}; **OR**
 - Hematologic conditions, including **ANY** of the following:
 - Thrombocytopenia with recent platelet count less than 100,000/microL²¹; **OR**

- Neurological or neuromuscular conditions, including ANY of the following^{22,23}:
 - History of cerebrovascular accident (CVA) within 6 months of planned surgical procedure; **OR**
 - Recent stroke or transient ischemic attack (TIA) within 90 days of planned surgical procedure; **OR**
 - Multiple sclerosis (MS) with acute symptom worsening or documented increased perioperative risk²⁴; **OR**
 - Amyotrophic lateral sclerosis (ALS); **OR**
 - Muscular dystrophy; **OR**
- Chronic, prescription high-dose opioid use^{25,26}; **OR**
- Body mass index (BMI) greater than 40 with documentation of additional medical complexities necessitating inpatient care²⁷⁻²⁹; **OR**
- The patient has documented evidence, including objective screening, of severe dementia³⁰⁻³²; **OR**
- The patient is pregnant or within 6 weeks post-partum and has a documented pregnancy-related risk factor necessitating inpatient care (e.g., increased risk of aspiration, thromboembolism, or need for maternal or fetal monitoring).^{33,34}

Medical Evidence

Determination of the appropriate level of care for elective surgical services involves consideration of several patient- and procedure-specific factors. The American Society of Anesthesiologists (ASA) Physical Status Classification System is a widely used preoperative evaluation tool, and has been successfully used in adult patients for over 60 years.⁸ A patient's physical status may be determined at several time points prior to the procedure, with the final assessment occurring on the day of surgery. Ferrari et al. (2021) identified that this system is not reliable for use in pediatric patients, notably in the presence of acute illness, and in determining how well a chronic condition was controlled; therefore, the ASA criteria should be reserved for adults.⁵

Bhat et al. (2024) reviewed perioperative management in patients with neuromuscular disorders. The authors note that these patients may be particularly vulnerable to postoperative complications, including aspiration and respiratory compromise, pneumonia, sepsis, and bleeding.²³ Recommendations for postoperative care included postural positioning to mitigate potential respiratory complications, consideration of specific metabolic factors that may be further exacerbated by blood loss and fluid replacement therapy, secretion management in patients unable to self-manage secretions, mitigation of extubation failure risks, and consideration of complications and adverse effects from pain and nausea control medications. These and other potentially serious postoperative complications led the authors to conclude that specific and detailed postoperative plans should be developed and implemented for all patients with neuromuscular disorders.

Hedge et al. (2017) reviewed ischemic heart disease and associated risk factors in elective surgery patients. They found that these patients are prone to myocardial infarction and arrhythmias during surgery; therefore, a thorough preoperative evaluation is needed, and any modifiable risk factors should be corrected prior to surgery.¹¹

Sethuraman et al. (2022) provided a narrative review of studies of Hemoglobin A1c (HgbA1c) levels within 8-12 weeks of surgery. While there is no consensus, they suggested HgbA1c levels should be checked prior to elective surgery and recommend a cut-off level of HgbA1c less than 8, with consideration of a lower cut-off of less than 7 for spine and joint replacement surgeries and cardiac surgeries.^{[14](#)}

Madsen et al. (2023) discuss the additional risks associated with surgery in obese patients. These include longer operative times with higher adjusted odds of developing infection, venous thromboembolism, and renal complications.^{[28](#)}

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Policy Revision History/Information

Original Date: July 30, 2024		
Review History		
Version 2	08/28/2025	Annual review. Policy title changed. Formerly "Site of Service Criteria for Inpatient vs. Outpatient Services". Added indications for procedures on the Medicare IPO list, done in conjunction with such a procedure, and procedures not considered low risk. Added indications for procedures or patients with high probability of complex wound care, advanced dementia, pregnancy, and post-partum. Refined and clarified criteria for ASA physical classification, diabetes, MS, addiction, high BMI. Removed criteria for cardiac arrhythmia, hypertension, obstructive sleep apnea, bleeding disorders, sickle cell disease, oxygen dependence. Reorganized criteria for clarity and ease-of-use. Added description section. References added and updated throughout. Literature review - Medical Evidence section updated (Bhat et al., 2024).



Cohere Medical Administrative Policy – Category III CPT Codes

Clinical Policy for Medical Necessity Review

Version: 1

Cohere Health UMC Approval Date: July 31, 2025

Last Annual Review: Not Applicable

Revision: Not Applicable

Next Annual Review: July 31, 2026

Important Notices

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Policy Information:

Specialty Area: Other - Administrative

Policy Name: Cohere Medical Administrative Policy - Category III CPT Codes

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Category III CPT Codes

Overview

This policy applies to all lines of business, including Medicare Advantage plans.

The American Medical Association (AMA) is responsible for the development of Current Procedural Terminology (CPT) Category III codes to track the utilization of emerging technologies, services, and procedures. The Category III CPT code description does not establish a service or procedure as safe, effective, or applicable to the clinical practice of medicine.^{1,2} The codes apply to a procedure or service that is (or has been) performed in a patient and any of the following³:

- There is support by at least 1 CPT or Health Care Professionals Advisory Committee (HCPAC) member that represents providers who would use the procedure or service; or
- The potential or actual clinical efficacy is supported by evidence-based, peer-reviewed literature; or
- There is at least 1 approved study protocol by an Institutional Review Board (IRB) for the study of the procedure or service; a current trial in the United States (ongoing or current) that outlines efficacy; or other evidence of clinical utilization.

Section 1862(a)(1)(A) of the Social Security Act (SSA) is the statutory basis for denying payment for types of care, items, services, and procedures, not excluded by any other statutory clause while meeting all technical requirements for coverage, that are determined to be any of the following¹:

1. Not generally accepted by the medical community as safe and effective in the setting and for the condition for which it is used;
2. Not proven safe and effective based on peer review or scientific literature;
3. Experimental;

4. Not medically necessary for a particular patient;
5. Furnished at a level, duration, or frequency that is not medically appropriate;
6. Not furnished in accordance with accepted standards of medical practice; or
7. Not furnished in a setting appropriate to the patient's medical needs and condition.

Items and services must be established as safe and effective to be considered medically necessary. That is, the items and services must be¹:

1. Consistent with the symptoms of diagnosis of the illness or injury under treatment; and
2. Necessary for, and consistent with, generally accepted professional medical standards of care (e.g., not experimental) and;
3. Not furnished primarily for the convenience of the patient, the provider or supplier; and
4. Furnished at the most appropriate level of care that can be provided safely and effectively to the patient.

Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational and are not considered reasonable and necessary under SSA 1862(a)(1)(A). Medicare payment, therefore, may not be made for procedures performed using devices that have not been approved for marketing by the FDA unless performed within the context of a clinical trial qualifying under the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) or in approved FDA Investigational Device Exemption (IDE) trial.¹

Applicable policies that consider a CPT Category III code medically necessary are noted in the coding table below. Due to the frequency of updates by the AMA and Centers for Medicare & Medicaid Services (CMS), the codes listed in this policy may not be all-inclusive. Codes that are deleted and not effective at the designated time of service may be ineligible for reimbursement.

Medical Necessity Criteria

Cohere Health considers the codes listed within this policy to be clinically unproven and not medically necessary due to inconclusive evidence of its effectiveness. In specific instances, a procedure may be covered when there is evidence-based guidance addressing the indications associated with a category III code. This includes, but is not limited to:

- Centers for Medicare & Medicaid (CMS) Services National or Local Coverage Determinations (NCDs or LCDs)
- State-specific guidance
- Clinical policy authored by Cohere Health
- Third party criteria as delegated by the Health Plan

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description	Conclusion
0042T	Cerebral perfusion analysis using computed tomography with contrast administration, including post-processing of parametric maps with determination of cerebral blood flow, cerebral blood volume, and mean transit time	Not Covered
0054T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on fluoroscopic images (List separately in addition to code for primary procedure)	Not Covered
0055T	Computer-assisted musculoskeletal surgical navigational orthopedic procedure, with image-guidance based on CT/MRI images (List separately in addition to code for primary procedure)	Not Covered
0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue	Not Covered
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue	Not Covered

0075T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; initial vessel	Not Covered
0076T	Transcatheter placement of extracranial vertebral artery stent(s), including radiologic supervision and interpretation, open or percutaneous; each additional vessel (List separately in addition to code for primary procedure)	Not Covered
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)	See <i>Total Disc Arthroplasty</i> or <i>Medicare Advantage Total Disc Arthroplasty</i>
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)	See <i>Total Disc Arthroplasty</i> or <i>Medicare Advantage Total Disc Arthroplasty</i>
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intraocular retinal electrode array, with vitrectomy	Not Covered
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified	Not Covered
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle	Not Covered
0106T	Quantitative sensory testing (QST), testing and interpretation per extremity; using touch pressure stimuli to assess large diameter sensation	Not Covered
0107T	Quantitative sensory testing (QST), testing and interpretation per extremity; using vibration stimuli to assess large diameter fiber sensation	Not Covered
0108T	Quantitative sensory testing (QST), testing and interpretation per extremity; using cooling stimuli to assess small nerve fiber sensation and hyperalgesia	Not Covered
0109T	Quantitative sensory testing (QST), testing and interpretation per extremity; using heat-pain stimuli to assess small nerve fiber sensation and hyperalgesia	Not Covered
0110T	Quantitative sensory testing (QST), testing and interpretation per extremity; using other stimuli to	Not Covered

	assess sensation	
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)	See <i>Total Disc Arthroplasty</i> or <i>Medicare Advantage Total Disc Arthroplasty</i>
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)	See <i>Total Disc Arthroplasty</i> or <i>Medicare Advantage Total Disc Arthroplasty</i>
0174T	Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation (List separately in addition to code for primary procedure)	Not Covered
0175T	Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation	Not Covered
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, TEMS), including muscularis propria (ie, full thickness)	Not Covered
0198T	Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report	Not Covered
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed	Not Covered
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed	Not Covered
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy,	See <i>Total Disc Arthroplasty</i> or

	laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	<i>Medicare Advantage Total Disc Arthroplasty</i>
0207T	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral	Not Covered
0208T	Pure tone audiometry (threshold), automated; air only	Not Covered
0209T	Pure tone audiometry (threshold), automated; air and bone	Not Covered
0210T	Speech audiometry threshold, automated;	Not Covered
0211T	Speech audiometry threshold, automated; with speech recognition	Not Covered
0212T	Comprehensive audiometry threshold evaluation and speech recognition (0209T, 0211T combined), automated	Not Covered
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level	<i>See Facet Injections or Medicare Advantage Facet Injections</i>
0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (List separately in addition to code for primary procedure)	<i>See Facet Injections or Medicare Advantage Facet Injections</i>
0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)	<i>See Facet Injections or Medicare Advantage Facet Injections</i>
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level	<i>See Facet Injections or Medicare Advantage Facet Injections</i>
0217T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (List separately in addition to code for primary	<i>See Facet Injections or Medicare Advantage Facet Injections</i>

	procedure)	
0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)	See <i>Facet Injections</i> or <i>Medicare Advantage Facet Injections</i>
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	See <i>Facet Injections</i> or <i>Medicare Advantage Facet Injections</i>
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	See <i>Facet Injections</i> or <i>Medicare Advantage Facet Injections</i>
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar	See <i>Facet Injections</i> or <i>Medicare Advantage Facet Injections</i>
0222T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure)	See <i>Facet Injections</i> or <i>Medicare Advantage Facet Injections</i>
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	Not Covered
0234T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; renal artery	See <i>Peripheral Atherectomy, Non-Lower Extremity</i>
0235T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; visceral artery (except renal), each vessel	See <i>Peripheral Atherectomy, Non-Lower Extremity</i>
0236T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; abdominal aorta	See <i>Peripheral Atherectomy, Non-Lower Extremity</i>

0237T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; brachiocephalic trunk and branches, each vessel	See <i>Peripheral Atherectomy, Non-Lower Extremity</i>
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel	See <i>Lower Extremity Arterial Revascularization or Medicare Advantage Lower Extremity Arterial Revascularization</i>
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space	Not Covered
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest	Not Covered
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest	Not Covered
0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy	Not Covered
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	See <i>Carotid Sinus Stimulators</i>
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	See <i>Carotid Sinus Stimulators</i>
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	See <i>Carotid Sinus Stimulators</i>

0269T	Revision or removal of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	See <i>Carotid Sinus Stimulators</i>
0270T	Revision or removal of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	See <i>Carotid Sinus Stimulators</i>
0271T	Revision or removal of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	See <i>Carotid Sinus Stimulators</i>
0272T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day);	See <i>Carotid Sinus Stimulators</i>
0273T	Interrogation device evaluation (in person), carotid sinus baroreflex activation system, including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming	See <i>Carotid Sinus Stimulators</i>
0274T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic	See <i>Spinal Decompression (Laminectomy, Laminotomy, Foraminotomy, and Discectomy)</i> or <i>Medicare Advantage Spinal Decompression (Laminectomy, Laminotomy, Foraminotomy, and Discectomy)</i>

0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar	See <i>Spinal Decompression (Laminectomy, Laminotomy, Foraminotomy, and Discectomy)</i> or <i>Medicare Advantage Spinal Decompression (Laminectomy, Laminotomy, Foraminotomy, and Discectomy)</i>
0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)	Not Covered
0308T	Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis	Not Covered
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report	Not Covered
0330T	Tear film imaging, unilateral or bilateral, with interpretation and report	Not Covered
0331T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment;	Not Covered
0332T	Myocardial sympathetic innervation imaging, planar qualitative and quantitative assessment; with tomographic SPECT	Not Covered
0333T	Visual evoked potential, screening of visual acuity, automated, with report	Not Covered
0335T	Insertion of sinus tarsi implant	Not Covered
0338T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral	Not Covered
0339T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture,	Not Covered

	selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; bilateral	
0342T	Therapeutic apheresis with selective HDL delipidation and plasma reinfusion	Not Covered
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus	See <i>Transcatheter Mitral Valve Repair</i> or <i>Medicare Advantage Transcatheter Mitral Valve Repair</i>
0347T	Placement of interstitial device(s) in bone for radiostereometric analysis (RSA)	Not Covered
0348T	Radiologic examination, radiostereometric analysis (RSA); spine, (includes cervical, thoracic and lumbosacral, when performed)	Not Covered
0349T	Radiologic examination, radiostereometric analysis (RSA); upper extremity(ies), (includes shoulder, elbow, and wrist, when performed)	Not Covered
0350T	Radiologic examination, radiostereometric analysis (RSA); lower extremity(ies), (includes hip, proximal femur, knee, and ankle, when performed)	Not Covered
0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real-time intraoperative	Not Covered
0352T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real-time or referred	Not Covered
0353T	Optical coherence tomography of breast, surgical cavity; real-time intraoperative	Not Covered
0354T	Optical coherence tomography of breast, surgical cavity; interpretation and report, real-time or referred	Not Covered
0358T	Bioelectrical impedance analysis whole body composition assessment, with interpretation and report	Not Covered
0362T	Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components:	Not Covered

	administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	
0373T	Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	Not Covered
0378T	Visual field assessment, with concurrent real time data analysis and accessible data storage with patient initiated data transmitted to a remote surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional	Not Covered
0379T	Visual field assessment, with concurrent real time data analysis and accessible data storage with patient initiated data transmitted to a remote surveillance center for up to 30 days; technical support and patient instructions, surveillance, analysis, and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional	Not Covered
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed	Not Covered
0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed	Not Covered
0397T	Endoscopic retrograde cholangiopancreatography (ERCP), with optical endomicroscopy (List separately in addition to code for primary procedure)	Not Covered
0398T	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed	Not Covered

0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium, when performed, and intraoperative pachymetry, when performed	Not Covered
0403T	Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting, minimum 60 minutes, per day	Not Covered
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	Not Covered
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes	See <i>Cardiac Contractility Modulation</i> or <i>Medicare Advantage Cardiac Contractility Modulation</i>
0409T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only	See <i>Cardiac Contractility Modulation</i> or <i>Medicare Advantage Cardiac Contractility Modulation</i>
0410T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only	See <i>Cardiac Contractility Modulation</i> or <i>Medicare Advantage Cardiac Contractility Modulation</i>
0411T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only	See <i>Cardiac Contractility Modulation</i> or <i>Medicare Advantage Cardiac Contractility Modulation</i>
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only	See <i>Cardiac Contractility</i>

		<i>Modulation or Medicare Advantage Cardiac Contractility Modulation</i>
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular)	<i>See Cardiac Contractility Modulation or Medicare Advantage Cardiac Contractility Modulation</i>
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only	<i>See Cardiac Contractility Modulation or Medicare Advantage Cardiac Contractility Modulation</i>
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode (atrial or ventricular lead)	<i>See Cardiac Contractility Modulation or Medicare Advantage Cardiac Contractility Modulation</i>
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator	<i>See Cardiac Contractility Modulation or Medicare Advantage Cardiac Contractility Modulation</i>
0417T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation system	<i>See Cardiac Contractility Modulation or Medicare Advantage Cardiac Contractility</i>

		<i>Modulation</i>
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system	See <i>Cardiac Contractility Modulation</i> or <i>Medicare Advantage Cardiac Contractility Modulation</i>
0419T	Destruction of neurofibroma, extensive (cutaneous, dermal extending into subcutaneous); face, head and neck, greater than 50 neurofibromas	Not Covered
0420T	Destruction of neurofibroma, extensive (cutaneous, dermal extending into subcutaneous); trunk and extremities, extensive, greater than 100 neurofibromas	Not Covered
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)	Not Covered
0422T	Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral	Not Covered
0424T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)	Not Covered
0425T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only	Not Covered
0426T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only	Not Covered
0427T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only	Not Covered
0428T	Removal of neurostimulator system for treatment of central sleep apnea; pulse generator only	Not Covered
0429T	Removal of neurostimulator system for treatment of central sleep apnea; sensing lead only	Not Covered

0430T	Removal of neurostimulator system for treatment of central sleep apnea; stimulation lead only	Not Covered
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only	Not Covered
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only	Not Covered
0433T	Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only	Not Covered
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea	Not Covered
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	Not Covered
0436T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study	Not Covered
0437T	Implantation of non-biologic or synthetic implant (eg, polypropylene) for fascial reinforcement of the abdominal wall (List separately in addition to code for primary procedure)	Not Covered
0439T	Myocardial contrast perfusion echocardiography, at rest or with stress, for assessment of myocardial ischemia or viability (List separately in addition to code for primary procedure)	Not Covered
0440T	Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve	Not Covered
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve	Not Covered
0442T	Ablation, percutaneous, cryoablation, includes imaging guidance; nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve)	Not Covered
0443T	Real-time spectral analysis of prostate tissue by fluorescence spectroscopy, including imaging guidance (List separately in addition to code for primary procedure)	Not Covered
0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training,	Not Covered

	and insertion, unilateral or bilateral	
0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral	Not Covered
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	Not Covered
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	Not Covered
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	Not Covered
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device	Not Covered
0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)	Not Covered
0464T	Visual evoked potential, testing for glaucoma, with interpretation and report	Not Covered
0465T	Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)	Not Covered
0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral	Not Covered
0472T	Device evaluation, interrogation, and initial programming of intraocular retinal electrode array (eg, retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional	Not Covered
0473T	Device evaluation and interrogation of intraocular retinal electrode array (eg, retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional	Not Covered
0474T	Insertion of anterior segment aqueous drainage	Not Covered

	device, with creation of intraocular reservoir, internal approach, into the supraciliary space	
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm2 or part thereof, or 1% of body surface area of infants and children	Not Covered
0480T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; each additional 100 cm2, or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)	Not Covered
0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed	Not Covered
0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed	Not Covered
0484T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)	Not Covered
0485T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; unilateral	Not Covered
0486T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; bilateral	Not Covered
0488T	Preventive behavior change, online/electronic structured intensive program for prevention of diabetes using a standardized diabetes prevention program curriculum, provided to an individual, per 30 days	Not Covered
0489T	Autologous adipose-derived regenerative cell therapy for scleroderma in the hands; adipose tissue harvesting, isolation and preparation of harvested cells including incubation with cell dissociation enzymes, removal of non-viable cells and debris, determination of concentration and dilution of regenerative cells	Not Covered
0490T	Autologous adipose-derived regenerative cell therapy for scleroderma in the hands; multiple injections in one or both hands	Not Covered

0494T	Surgical preparation and cannulation of marginal (extended) cadaver donor lung(s) to ex vivo organ perfusion system, including decannulation, separation from the perfusion system, and cold preservation of the allograft prior to implantation, when performed	Not Covered
0495T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; first two hours in sterile field	Not Covered
0496T	Initiation and monitoring marginal (extended) cadaver donor lung(s) organ perfusion system by physician or qualified health care professional, including physiological and laboratory assessment (eg, pulmonary artery flow, pulmonary artery pressure, left atrial pressure, pulmonary vascular resistance, mean/peak and plateau airway pressure, dynamic compliance and perfusate gas analysis), including bronchoscopy and X ray when performed; each additional hour (List separately in addition to code for primary procedure)	Not Covered
0499T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound	Not Covered
0500T	Infectious agent detection by nucleic acid (DNA or RNA), Human Papillomavirus (HPV) for five or more separately reported high-risk HPV types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) (ie, genotyping)	Not Covered
0501T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound	Not Covered
0502T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral	Not Covered

	stricture or stenosis, including fluoroscopy, when performed	
0503T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report	Not Covered
0504T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission	Not Covered
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	See Lower Extremity Arterial Revascularization or Medicare Advantage Lower Extremity Arterial Revascularization
0506T	Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report	Not Covered
0507T	Near infrared dual imaging (ie, simultaneous reflective and transilluminated light) of meibomian glands, unilateral or bilateral, with interpretation and report	Not Covered
0508T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of	Not Covered

	coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model	
0509T	Electroretinography (ERG) with interpretation and report, pattern (PERG)	Not Covered
0510T	Removal of sinus tarsi implant	Not Covered
0511T	Removal and reinsertion of sinus tarsi implant	Not Covered
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound	Not Covered
0513T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)	Not Covered
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	Not Covered
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	Not Covered
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; both components of pulse generator (battery and transmitter) only	Not Covered
0518T	Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing; battery component only	Not Covered
0519T	Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; both components (battery and transmitter)	Not Covered
0520T	Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; battery component only	Not Covered

0521T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing	Not Covered
0522T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, wireless cardiac stimulator for left ventricular pacing	Not Covered
0523T	Intraprocedural coronary fractional flow reserve (FFR) with 3D functional mapping of color-coded FFR values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (List separately in addition to code for primary procedure)	Not Covered
0524T	Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring	Not Covered
0525T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)	Not Covered
0526T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; electrode only	Not Covered
0527T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only	Not Covered
0528T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	Not Covered
0529T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	Not Covered

0530T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)	Not Covered
0531T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; electrode only	Not Covered
0532T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; implantable monitor only	Not Covered
0533T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report	Not Covered
0534T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	Not Covered
0535T	Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; includes set-up, patient training, configuration of monitor, data upload, analysis and initial report configuration, download review, interpretation and report	Not Covered
0536T	Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; set-up, patient training, configuration of monitor	Not Covered
0537T	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day	Not Covered
0538T	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)	Not Covered
0539T	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration	Not Covered
0540T	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous	Not Covered

0541T	Myocardial imaging by magnetocardiography (MCG) for detection of cardiac ischemia, by signal acquisition using minimum 36 channel grid, generation of magnetic-field time-series images, quantitative analysis of magnetic dipoles, machine learning-derived clinical scoring, and automated report generation, single study;	Not Covered
0542T	Myocardial imaging by magnetocardiography (MCG) for detection of cardiac ischemia, by signal acquisition using minimum 36 channel grid, generation of magnetic-field time-series images, quantitative analysis of magnetic dipoles, machine learning-derived clinical scoring, and automated report generation, single study; interpretation and report	Not Covered
0543T	Transapical mitral valve repair, including transthoracic echocardiography, when performed, with placement of artificial chordae tendineae	Not Covered
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture	Not Covered
0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach	Not Covered
0546T	Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report	Not Covered
0547T	Bone-material quality testing by microindentation(s) of the tibia(s), with results reported as a score	Not Covered
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional	Not Covered
0553T	Percutaneous transcatheter placement of iliac arteriovenous anastomosis implant, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention	Not Covered
0554T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography	Not Covered

	scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone-mineral density, interpretation and report	
0555T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data	Not Covered
0556T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone-mineral density	Not Covered
0557T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; interpretation and report	Not Covered
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis	Not Covered
0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure	Not Covered
0560T	Anatomic model 3D-printed from image data set(s); each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure)	Not Covered
0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide	Not Covered
0562T	Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)	Not Covered
0563T	Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral	Not Covered
0564T	Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on percent of cytotoxicity observed, a minimum of 14 drugs or drug combinations	Not Covered

0565T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation	Not Covered
0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral	Not Covered
0567T	Permanent fallopian tube occlusion with degradable biopolymer implant, transcervical approach, including transvaginal ultrasound	Not Covered
0568T	Introduction of mixture of saline and air for sonosalpingography to confirm occlusion of fallopian tubes, transcervical approach, including transvaginal ultrasound and pelvic ultrasound	Not Covered
0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis	Not Covered
0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure)	Not Covered
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed	See <i>Cardiac Implantable Devices</i> or <i>Medicare Advantage Cardiac Implantable Devices</i>
0572T	Insertion of substernal implantable defibrillator electrode	See <i>Cardiac Implantable Devices</i> or <i>Medicare Advantage Cardiac Implantable Devices</i>
0573T	Removal of substernal implantable defibrillator electrode	See <i>Cardiac Implantable Devices</i> or <i>Medicare Advantage Cardiac</i>

		<i>Implantable Devices</i>
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode	See <i>Cardiac Implantable Devices</i> or <i>Medicare Advantage Cardiac Implantable Devices</i>
0575T	Programming device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional	Not Covered
0576T	Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter	Not Covered
0577T	Electrophysiologic evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	See <i>Cardiac Implantable Devices</i> or <i>Medicare Advantage Cardiac Implantable Devices</i>
0578T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional	Not Covered
0579T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	Not Covered
0580T	Removal of substernal implantable defibrillator pulse generator only	See <i>Cardiac Implantable</i>

		<i>Devices or Medicare Advantage Cardiac Implantable Devices</i>
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	Not Covered
0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance	Not Covered
0583T	Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia	Not Covered
0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous	Not Covered
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic	Not Covered
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open	Not Covered
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	Not Covered
0588T	Revision or removal of percutaneously placed integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	Not Covered
0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system for bladder dysfunction (eg, electrode array and	Not Covered

	receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters	
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system for bladder dysfunction (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters	Not Covered
0591T	Health and well-being coaching face-to-face; individual, initial assessment	Not Covered
0592T	Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes	Not Covered
0593T	Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes	Not Covered
0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	Not Covered
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	Not Covered
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	Not Covered
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)	Not Covered
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for	Not Covered

	primary procedure)	
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	Not Covered
0601T	Ablation, irreversible electroporation; 1 or more tumors per organ, including fluoroscopic and ultrasound guidance, when performed, open	Not Covered
0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent	Not Covered
0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours	Not Covered
0604T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center, unilateral or bilateral; initial device provision, set-up and patient education on use of equipment	Not Covered
0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center, unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days	Not Covered
0606T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center, unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days	Not Covered
0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment	Not Covered
0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including	Not Covered

	measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional	
0609T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie, lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs	Not Covered
0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis	Not Covered
0611T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs	Not Covered
0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report	Not Covered
0613T	Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed	Not Covered
0614T	Removal and replacement of substernal implantable defibrillator pulse generator	See <i>Cardiac Implantable Devices</i> or <i>Medicare Advantage Cardiac Implantable Devices</i>
0615T	Automated analysis of binocular eye movements without spatial calibration, including disconjugacy, saccades, and pupillary dynamics for the assessment of concussion, with interpretation and report	Not Covered
0616T	Insertion of iris prosthesis, including suture fixation	Not Covered

	and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens	
0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	Not Covered
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	Not Covered
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	Not Covered
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	Not Covered
0621T	Trabeculostomy ab interno by laser;	Not Covered
0622T	Trabeculostomy ab interno by laser; with use of ophthalmic endoscope	Not Covered
0623T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report	Not Covered
0624T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission	Not Covered
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity	Not Covered

	of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	
0626T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report	Not Covered
0627T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level	See <i>Spinal Allogeneic Tissue-Based Injections</i>
0628T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)	See <i>Spinal Allogeneic Tissue-Based Injections</i>
0629T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level	See <i>Spinal Allogeneic Tissue-Based Injections</i>
0630T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)	See <i>Spinal Allogeneic Tissue-Based Injections</i>
0631T	Transcutaneous visible light hyperspectral imaging measurement of oxyhemoglobin, deoxyhemoglobin, and tissue oxygenation, with interpretation and report, per extremity	Not Covered
0632T	Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance	See <i>Pulmonary Artery Denervation (PADN) or Medicare Advantage Pulmonary Artery Denervation (PADN)</i>
0633T	Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast material	Not Covered

0634T	Computed tomography, breast, including 3D rendering, when performed, unilateral; with contrast material(s)	Not Covered
0635T	Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast, followed by contrast material(s)	Not Covered
0636T	Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast material(s)	Not Covered
0637T	Computed tomography, breast, including 3D rendering, when performed, bilateral; with contrast material(s)	Not Covered
0638T	Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast, followed by contrast material(s)	Not Covered
0639T	Wireless skin sensor thermal anisotropy measurement(s) and assessment of flow in cerebrospinal fluid shunt, including ultrasound guidance, when performed	Not Covered
0640T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; first anatomic site	Not Covered
0641T	Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; data upload, analysis and initial report configuration	Not Covered
0642T	Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; download review, interpretation and report	Not Covered
0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach	Not Covered
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	Not Covered

0645T	Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed	Not Covered
0646T	Transcatheter tricuspid valve implantation (TTVI)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	Not Covered
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	Not Covered
0648T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; single organ	Not Covered
0649T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure); single organ (List separately in addition to code for primary procedure)	Not Covered
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional	Not Covered
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report	See <i>Capsule Endoscopy</i> or <i>Medicare Advantage Capsule Endoscopy</i>

0652T	Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	Not Covered
0653T	Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple	Not Covered
0654T	Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter	Not Covered
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	Not Covered
0656T	Anterior lumbar or thoracolumbar vertebral body tethering; up to 7 vertebral segments	See <i>Pediatric Vertebral Body Tethering, Medicare Advantage Pediatric Vertebral Body Tethering, Vertebral Body Tethering, or Medicare Advantage Vertebral Body Tethering</i>
0657T	Anterior lumbar or thoracolumbar vertebral body tethering; 8 or more vertebral segments	See <i>Pediatric Vertebral Body Tethering, Medicare Advantage Pediatric Vertebral Body Tethering, Vertebral Body Tethering, or Medicare Advantage Vertebral Body Tethering</i>
0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score	Not Covered
0659T	Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization during acute myocardial infarction, including catheter	Not Covered

	placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation	
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach	Not Covered
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant	Not Covered
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	Not Covered
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)	Not Covered
0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor	Not Covered
0665T	Donor hysterectomy (including cold preservation); open, from living donor	Not Covered
0666T	Donor hysterectomy (including cold preservation); laparoscopic or robotic, from living donor	Not Covered
0667T	Donor hysterectomy (including cold preservation); recipient uterus allograft transplantation from cadaver or living donor	Not Covered
0668T	Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary	Not Covered
0669T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each	Not Covered
0670T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; arterial anastomosis, each	Not Covered
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more	Not Covered
0672T	Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence	Not Covered

0673T	Ablation, benign thyroid nodule(s), percutaneous, laser, including imaging guidance	Not Covered
0674T	Laparoscopic insertion of new or replacement of permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including an implantable pulse generator and diaphragmatic lead(s)	Not Covered
0675T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first lead	Not Covered
0676T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional lead (List separately in addition to code for primary procedure)	Not Covered
0677T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first repositioned lead	Not Covered
0678T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional repositioned lead (List separately in addition to code for primary procedure)	Not Covered
0679T	Laparoscopic removal of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	Not Covered
0680T	Insertion or replacement of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing lead(s)	Not Covered
0681T	Relocation of pulse generator only, permanent implantable synchronized diaphragmatic	Not Covered

	stimulation system for augmentation of cardiac function, with connection to existing dual leads	
0682T	Removal of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	Not Covered
0683T	Programming device evaluation (in-person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	Not Covered
0684T	Peri-procedural device evaluation (in-person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review, and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	Not Covered
0685T	Interrogation device evaluation (in-person) with analysis, review and report by a physician or other qualified health care professional, including connection, recording and disconnection per patient encounter, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	Not Covered
0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	Not Covered
0687T	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session	Not Covered
0688T	Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified health care professional, with report, per calendar month	Not Covered
0689T	Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained without diagnostic ultrasound examination of the same anatomy (eg, organ, gland, tissue, target structure)	Not Covered

0690T	Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained with diagnostic ultrasound examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	Not Covered
0691T	Automated analysis of an existing computed tomography study for vertebral fracture(s), including assessment of bone density when performed, data preparation, interpretation, and report	Not Covered
0692T	Therapeutic ultrafiltration	Not Covered
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	Not Covered
0694T	3-dimensional volumetric imaging and reconstruction of breast or axillary lymph node tissue, each excised specimen, 3-dimensional automatic specimen reorientation, interpretation and report, real-time intraoperative	Not Covered
0695T	Body surface-activation mapping of pacemaker or pacing cardioverter-defibrillator lead(s) to optimize electrical synchrony, cardiac resynchronization therapy device, including connection, recording, disconnection, review, and report; at time of implant or replacement	Not Covered
0696T	Body surface-activation mapping of pacemaker or pacing cardioverter-defibrillator lead(s) to optimize electrical synchrony, cardiac resynchronization therapy device, including connection, recording, disconnection, review, and report; at time of follow-up interrogation or programming device evaluation	Not Covered
0697T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; multiple organs	Not Covered
0698T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data	Not Covered

	preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure); multiple organs (List separately in addition to code for primary procedure)	
0699T	Injection, posterior chamber of eye, medication	Not Covered
0700T	Molecular fluorescent imaging of suspicious nevus; first lesion	Not Covered
0701T	Molecular fluorescent imaging of suspicious nevus; each additional lesion (List separately in addition to code for primary procedure)	Not Covered
0704T	Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment	Not Covered
0705T	Remote treatment of amblyopia using an eye tracking device; surveillance center technical support including data transmission with analysis, with a minimum of 18 training hours, each 30 days	Not Covered
0706T	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified health care professional, per calendar month	Not Covered
0707T	Injection(s), bone-substitute material (eg, calcium phosphate) into subchondral bone defect (ie, bone marrow lesion, bone bruise, stress injury, microtrabecular fracture), including imaging guidance and arthroscopic assistance for joint visualization	See <i>Subchondroplasty</i> or <i>Medicare Advantage Subchondroplasty</i>
0708T	Intradermal cancer immunotherapy; preparation and initial injection	Not Covered
0709T	Intradermal cancer immunotherapy; each additional injection (List separately in addition to code for primary procedure)	Not Covered
0710T	Noninvasive arterial plaque analysis using software processing of data from non-coronary computerized tomography angiography; including data preparation and transmission, quantification of the structure and composition of the vessel wall and assessment for lipid-rich necrotic core plaque to assess atherosclerotic plaque stability, data review, interpretation and report	Not Covered
0711T	Noninvasive arterial plaque analysis using software	Not Covered

	processing of data from non-coronary computerized tomography angiography; data preparation and transmission	
0712T	Noninvasive arterial plaque analysis using software processing of data from non-coronary computerized tomography angiography; quantification of the structure and composition of the vessel wall and assessment for lipid-rich necrotic core plaque to assess atherosclerotic plaque stability	Not Covered
0713T	Noninvasive arterial plaque analysis using software processing of data from non-coronary computerized tomography angiography; data review, interpretation and report	Not Covered
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume less than 50 mL	Not Covered
0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)	See <i>Coronary Intravascular Lithotripsy (IVL)</i> or <i>Medicare Advantage Coronary Intravascular Lithotripsy (IVL)</i>
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score	Not Covered
0717T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; adipose tissue harvesting, isolation and preparation of harvested cells, including incubation with cell dissociation enzymes, filtration, washing, and concentration of ADRCs	Not Covered
0718T	Autologous adipose-derived regenerative cell (ADRC) therapy for partial thickness rotator cuff tear; injection into supraspinatus tendon including ultrasound guidance, unilateral	Not Covered
0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment	Not Covered
0720T	Percutaneous electrical nerve field stimulation,	Not Covered

	cranial nerves, without implantation	
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	Not Covered
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)	Not Covered
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session	Not Covered
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	Not Covered
0725T	Vestibular device implantation, unilateral	Not Covered
0726T	Removal of implanted vestibular device, unilateral	Not Covered
0727T	Removal and replacement of implanted vestibular device, unilateral	Not Covered
0728T	Diagnostic analysis of vestibular implant, unilateral; with initial programming	Not Covered
0729T	Diagnostic analysis of vestibular implant, unilateral; with subsequent programming	Not Covered
0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance	Not Covered
0731T	Augmentative AI-based facial phenotype analysis with report	Not Covered
0732T	Immunotherapy administration with electroporation, intramuscular	Not Covered

0733T	Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days	See <i>Physical and Occupational Therapy (PT/OT)</i> or <i>Medicare Advantage Physical and Occupational Therapy (PT/OT)</i>
0734T	Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; treatment management services by a physician or other qualified health care professional, per calendar month	See <i>Physical and Occupational Therapy (PT/OT)</i> or <i>Medicare Advantage Physical and Occupational Therapy (PT/OT)</i>
0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)	Not Covered
0736T	Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter	Not Covered
0737T	Xenograft implantation into the articular surface	See <i>Xenograft Implantation</i> or <i>Medicare Advantage Xenograft Implantation</i>
0738T	Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination	Not Covered
0739T	Ablation of malignant prostate tissue by magnetic field induction, including all intraprocedural, transperineal needle/catheter placement for nanoparticle installation and intraprocedural temperature monitoring, thermal dosimetry, bladder irrigation, and magnetic field nanoparticle activation	Not Covered
0740T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; initial set-up and patient	Not Covered

	education	
0741T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; provision of software, data collection, transmission, and storage, each 30 days	Not Covered
0742T	Absolute quantitation of myocardial blood flow (AQMBF), single-photon emission computed tomography (SPECT), with exercise or pharmacologic stress, and at rest, when performed (List separately in addition to code for primary procedure)	Not Covered
0743T	Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report	Not Covered
0744T	Insertion of bioprosthetic valve, open, femoral vein, including duplex ultrasound imaging guidance, when performed, including autogenous or nonautogenous patch graft (eg, polyester, ePTFE, bovine pericardium), when performed	Not Covered
0745T	Cardiac focal ablation utilizing radiation therapy for arrhythmia; noninvasive arrhythmia localization and mapping of arrhythmia site (nidus), derived from anatomical image data (eg, CT, MRI, or myocardial perfusion scan) and electrical data (eg, 12-lead ECG data), and identification of areas of avoidance	Not Covered
0746T	Cardiac focal ablation utilizing radiation therapy for arrhythmia; conversion of arrhythmia localization and mapping of arrhythmia site (nidus) into a multidimensional radiation treatment plan	Not Covered
0747T	Cardiac focal ablation utilizing radiation therapy for arrhythmia; delivery of radiation therapy, arrhythmia	Not Covered
0748T	Injections of stem cell product into perianal perirectal soft tissue, including fistula preparation (eg, removal of setons, fistula curettage, closure of internal openings)	Not Covered

0749T	Bone strength and fracture-risk assessment using digital X-ray radiogrammetry-bone mineral density (DXR-BMD) analysis of bone mineral density (BMD) utilizing data from a digital X ray, retrieval and transmission of digital X-ray data, assessment of bone strength and fracture risk and BMD, interpretation and report;	Not Covered
0750T	Bone strength and fracture-risk assessment using digital X-ray radiogrammetry-bone mineral density (DXR-BMD) analysis of bone mineral density (BMD) utilizing data from a digital X ray, retrieval and transmission of digital X-ray data, assessment of bone strength and fracture risk and BMD, interpretation and report; with single-view digital X-ray examination of the hand taken for the purpose of DXR-BMD	Not Covered
0751T	Digitization of glass microscope slides for level II, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure)	Not Covered
0752T	Digitization of glass microscope slides for level III, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure)	Not Covered
0753T	Digitization of glass microscope slides for level IV, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure)	Not Covered
0754T	Digitization of glass microscope slides for level V, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure)	Not Covered
0755T	Digitization of glass microscope slides for level VI, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure)	Not Covered
0756T	Digitization of glass microscope slides for special stain, including interpretation and report, group I, for microorganisms (eg, acid fast, methenamine silver) (List separately in addition to code for primary procedure)	Not Covered
0757T	Digitization of glass microscope slides for special stain, including interpretation and report, group II, all other (eg, iron, trichrome), except stain for	Not Covered

	microorganisms, stains for enzyme constituents, or immunocytochemistry and immunohistochemistry (List separately in addition to code for primary procedure)	
0758T	Digitization of glass microscope slides for special stain, including interpretation and report, histochemical stain on frozen tissue block (List separately in addition to code for primary procedure)	Not Covered
0759T	Digitization of glass microscope slides for special stain, including interpretation and report, group III, for enzyme constituents (List separately in addition to code for primary procedure)	Not Covered
0760T	Digitization of glass microscope slides for immunohistochemistry or immunocytochemistry, per specimen, initial single antibody stain procedure (List separately in addition to code for primary procedure)	Not Covered
0761T	Digitization of glass microscope slides for immunohistochemistry or immunocytochemistry, per specimen, each additional single antibody stain procedure (List separately in addition to code for primary procedure)	Not Covered
0762T	Digitization of glass microscope slides for immunohistochemistry or immunocytochemistry, per specimen, each multiplex antibody stain procedure (List separately in addition to code for primary procedure)	Not Covered
0763T	Digitization of glass microscope slides for morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure, manual (List separately in addition to code for primary procedure)	Not Covered
0764T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure)	Not Covered
0765T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg,	Not Covered

	low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram	
0766T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve	Not Covered
0767T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)	Not Covered
0768T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve	Not Covered
0769T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)	Not Covered
0770T	Virtual reality technology to assist therapy (List separately in addition to code for primary procedure)	Not Covered
0771T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older	Not Covered
0772T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified	Not Covered

	health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; each additional 15 minutes intraservice time (List separately in addition to code for primary service)	
0773T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; initial 15 minutes of intraservice time, patient age 5 years or older	Not Covered
0774T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; each additional 15 minutes intraservice time (List separately in addition to code for primary service)	Not Covered
0775T	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, includes placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s])	See <i>Sacroiliac Joint Fusion</i> or <i>Medicare Advantage Sacroiliac Joint Fusion</i>
0776T	Therapeutic induction of intra-brain hypothermia, including placement of a mechanical temperature-controlled cooling device to the neck over carotids and head, including monitoring (eg, vital signs and sport concussion assessment tool 5 [SCAT5]), 30 minutes of treatment	Not Covered
0777T	Real-time pressure-sensing epidural guidance system (List separately in addition to code for primary procedure)	Not Covered
0778T	Surface mechanomyography (sMMG) with concurrent application of inertial measurement unit (IMU) sensors for measurement of multi-joint range of motion, posture, gait, and muscle function	Not Covered
0779T	Gastrointestinal myoelectrical activity study, stomach through colon, with interpretation and	Not Covered

	report	
0780T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract	Not Covered
0781T	Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; bilateral mainstem bronchi	Not Covered
0782T	Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; unilateral mainstem bronchus	Not Covered
0783T	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment	Not Covered
0784T	Insertion or replacement of percutaneous electrode array, spinal, with integrated neurostimulator, including imaging guidance, when performed	Not Covered
0785T	Revision or removal of neurostimulator electrode array, spinal, with integrated neurostimulator	Not Covered
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed	Not Covered
0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator	Not Covered
0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters	Not Covered
0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive	Not Covered

	neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters	
0790T	Revision (eg, augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed	See <i>Pediatric Vertebral Body Tethering, Medicare Advantage Pediatric Vertebral Body Tethering, Vertebral Body Tethering, or Medicare Advantage Vertebral Body Tethering</i>
0791T	Motor-cognitive, semi-immersive virtual reality-facilitated gait training, each 15 minutes (List separately in addition to code for primary procedure)	Not Covered
0792T	Application of silver diamine fluoride 38%, by a physician or other qualified health care professional	Not Covered
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance	See <i>Pulmonary Artery Denervation (PADN) or Medicare Advantage Pulmonary Artery Denervation (PADN)</i>
0794T	Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately	Not Covered
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device	See <i>Leadless Cardiac Pacemakers or Medicare Advantage</i>

	evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	<i>Leadless Cardiac Pacemakers</i>
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)	<i>See Leadless Cardiac Pacemakers or Medicare Advantage Leadless Cardiac Pacemakers</i>
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	<i>See Leadless Cardiac Pacemakers or Medicare Advantage Leadless Cardiac Pacemakers</i>
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	<i>See Leadless Cardiac Pacemakers or Medicare Advantage Leadless Cardiac Pacemakers</i>
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component	<i>See Leadless Cardiac Pacemakers or Medicare Advantage Leadless Cardiac Pacemakers</i>
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	<i>See Leadless Cardiac Pacemakers or Medicare Advantage Leadless Cardiac Pacemakers</i>

0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)	See <i>Leadless Cardiac Pacemakers</i> or <i>Medicare Advantage Leadless Cardiac Pacemakers</i>
0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component	See <i>Leadless Cardiac Pacemakers</i> or <i>Medicare Advantage Leadless Cardiac Pacemakers</i>
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	See <i>Leadless Cardiac Pacemakers</i> or <i>Medicare Advantage Leadless Cardiac Pacemakers</i>
0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers	See <i>Leadless Cardiac Pacemakers</i> or <i>Medicare Advantage Leadless Cardiac Pacemakers</i>
0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach	Not Covered
0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach	Not Covered
0807T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with previously acquired computed tomography	Not Covered

	(CT) images, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report	
0808T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with computed tomography (CT) images taken for the purpose of pulmonary tissue ventilation analysis, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report	Not Covered
0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intraarticular implant(s), including allograft or synthetic device(s)	See <i>Sacroiliac Joint Fusion</i> or <i>Medicare Advantage Sacroiliac Joint Fusion</i>
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	Not Covered
0811T	Remote multi-day complex uroflowmetry (eg, calibrated electronic equipment); set-up and patient education on use of equipment	Not Covered
0812T	Remote multi-day complex uroflowmetry (eg, calibrated electronic equipment); device supply with automated report generation, up to 10 days	Not Covered
0813T	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon	Not Covered
0814T	Percutaneous injection of calcium-based biodegradable osteoconductive material, proximal femur, including imaging guidance, unilateral	Not Covered
0815T	Ultrasound-based radiofrequency echographic multi-spectrometry (REMS), bone-density study and fracture-risk assessment, 1 or more sites, hips, pelvis, or spine	Not Covered
0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous	Not Covered
0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction	Not Covered

	including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial	
0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous	Not Covered
0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial	Not Covered
0820T	Continuous in-person monitoring and intervention (eg, psychotherapy, crisis intervention), as needed, during psychedelic medication therapy; first physician or other qualified health care professional, each hour	Not Covered
0821T	Continuous in-person monitoring and intervention (eg, psychotherapy, crisis intervention), as needed, during psychedelic medication therapy; second physician or other qualified health care professional, concurrent with first physician or other qualified health care professional, each hour (List separately in addition to code for primary procedure)	Not Covered
0822T	Continuous in-person monitoring and intervention (eg, psychotherapy, crisis intervention), as needed, during psychedelic medication therapy; clinical staff under the direction of a physician or other qualified health care professional, concurrent with first physician or other qualified health care professional, each hour (List separately in addition to code for primary procedure)	Not Covered
0823T	Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	Not Covered
0824T	Transcatheter removal of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or	Not Covered

	right ventriculography, femoral venography, cavography), when performed	
0825T	Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	Not Covered
0826T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, leadless pacemaker system in single-cardiac chamber	Not Covered
0827T	Digitization of glass microscope slides for cytopathology, fluids, washings, or brushings, except cervical or vaginal; smears with interpretation (List separately in addition to code for primary procedure)	Not Covered
0828T	Digitization of glass microscope slides for cytopathology, fluids, washings, or brushings, except cervical or vaginal; simple filter method with interpretation (List separately in addition to code for primary procedure)	Not Covered
0829T	Digitization of glass microscope slides for cytopathology, concentration technique, smears, and interpretation (eg, Saccomanno technique) (List separately in addition to code for primary procedure)	Not Covered
0830T	Digitization of glass microscope slides for cytopathology, selective-cellular enhancement technique with interpretation (eg, liquid-based slide preparation method), except cervical or vaginal (List separately in addition to code for primary procedure)	Not Covered
0831T	Digitization of glass microscope slides for cytopathology, cervical or vaginal (any reporting system), requiring interpretation by physician (List separately in addition to code for primary procedure)	Not Covered
0832T	Digitization of glass microscope slides for	Not Covered

	cytopathology, smears, any other source; screening and interpretation (List separately in addition to code for primary procedure)	
0833T	Digitization of glass microscope slides for cytopathology, smears, any other source; preparation, screening and interpretation (List separately in addition to code for primary procedure)	Not Covered
0834T	Digitization of glass microscope slides for cytopathology, smears, any other source; extended study involving over 5 slides and/or multiple stains (List separately in addition to code for primary procedure)	Not Covered
0835T	Digitization of glass microscope slides for cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site (List separately in addition to code for primary procedure)	Not Covered
0836T	Digitization of glass microscope slides for cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site (List separately in addition to code for primary procedure)	Not Covered
0837T	Digitization of glass microscope slides for cytopathology, evaluation of fine needle aspirate; interpretation and report (List separately in addition to code for primary procedure)	Not Covered
0838T	Digitization of glass microscope slides for consultation and report on referred slides prepared elsewhere (List separately in addition to code for primary procedure)	Not Covered
0839T	Digitization of glass microscope slides for consultation and report on referred material requiring preparation of slides (List separately in addition to code for primary procedure)	Not Covered
0840T	Digitization of glass microscope slides for consultation, comprehensive, with review of records and specimens, with report on referred material (List separately in addition to code for primary procedure)	Not Covered
0841T	Digitization of glass microscope slides for pathology	Not Covered

	consultation during surgery; first tissue block, with frozen section(s), single specimen (List separately in addition to code for primary procedure)	
0842T	Digitization of glass microscope slides for pathology consultation during surgery; each additional tissue block with frozen section(s) (List separately in addition to code for primary procedure)	Not Covered
0843T	Digitization of glass microscope slides for pathology consultation during surgery; cytologic examination (eg, touch preparation, squash preparation), initial site (List separately in addition to code for primary procedure)	Not Covered
0844T	Digitization of glass microscope slides for pathology consultation during surgery; cytologic examination (eg, touch preparation, squash preparation), each additional site (List separately in addition to code for primary procedure)	Not Covered
0845T	Digitization of glass microscope slides for immunofluorescence, per specimen; initial single antibody stain procedure (List separately in addition to code for primary procedure)	Not Covered
0846T	Digitization of glass microscope slides for immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)	Not Covered
0847T	Digitization of glass microscope slides for examination and selection of retrieved archival (ie, previously diagnosed) tissue(s) for molecular analysis (eg, KRAS mutational analysis) (List separately in addition to code for primary procedure)	Not Covered
0848T	Digitization of glass microscope slides for in situ hybridization (eg, FISH), per specimen; initial single probe stain procedure (List separately in addition to code for primary procedure)	Not Covered
0849T	Digitization of glass microscope slides for in situ hybridization (eg, FISH), per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure)	Not Covered
0850T	Digitization of glass microscope slides for in situ hybridization (eg, FISH), per specimen; each	Not Covered

	multiplex probe stain procedure (List separately in addition to code for primary procedure)	
0851T	Digitization of glass microscope slides for morphometric analysis, in situ hybridization (quantitative or semiquantitative), manual, per specimen; initial single probe stain procedure (List separately in addition to code for primary procedure)	Not Covered
0852T	Digitization of glass microscope slides for morphometric analysis, in situ hybridization (quantitative or semiquantitative), manual, per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure)	Not Covered
0853T	Digitization of glass microscope slides for morphometric analysis, in situ hybridization (quantitative or semiquantitative), manual, per specimen; each multiplex probe stain procedure (List separately in addition to code for primary procedure)	Not Covered
0854T	Digitization of glass microscope slides for blood smear, peripheral, interpretation by physician with written report (List separately in addition to code for primary procedure)	Not Covered
0855T	Digitization of glass microscope slides for bone marrow, smear interpretation (List separately in addition to code for primary procedure)	Not Covered
0856T	Digitization of glass microscope slides for electron microscopy, diagnostic (List separately in addition to code for primary procedure)	Not Covered
0857T	Opto-acoustic imaging, breast, unilateral, including axilla when performed, real-time with image documentation, augmentative analysis and report (List separately in addition to code for primary procedure)	Not Covered
0858T	Externally applied transcranial magnetic stimulation with concomitant measurement of evoked cortical potentials with automated report	Not Covered
0859T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and	Not Covered

	report; each additional anatomic site (List separately in addition to code for primary procedure)	
0860T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), for screening for peripheral arterial disease, including provocative maneuvers, image acquisition, interpretation, and report, one or both lower extremities	Not Covered
0861T	Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing; both components (battery and transmitter)	Not Covered
0862T	Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; battery component only	Not Covered
0863T	Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; transmitter component only	Not Covered
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	Not Covered
0865T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion identification, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the brain during the same session	Not Covered
0866T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion detection, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the brain (List separately in addition to code for primary procedure)	Not Covered
0867T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate	Not Covered

	volume greater or equal to 50 mL	
0868T	High-resolution gastric electrophysiology mapping with simultaneous patient-symptom profiling, with interpretation and report	Not Covered
0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed	Not Covered
0870T	Implantation of subcutaneous peritoneal ascites pump system, percutaneous, including pump-pocket creation, insertion of tunneled indwelling bladder and peritoneal catheters with pump connections, including all imaging and initial programming, when performed	Not Covered
0871T	Replacement of a subcutaneous peritoneal ascites pump, including reconnection between pump and indwelling bladder and peritoneal catheters, including initial programming and imaging, when performed	Not Covered
0872T	Replacement of indwelling bladder and peritoneal catheters, including tunneling of catheter(s) and connection with previously implanted peritoneal ascites pump, including imaging and programming, when performed	Not Covered
0873T	Revision of a subcutaneously implanted peritoneal ascites pump system, any component (ascites pump, associated peritoneal catheter, associated bladder catheter), including imaging and programming, when performed	Not Covered
0874T	Removal of a peritoneal ascites pump system, including implanted peritoneal ascites pump and indwelling bladder and peritoneal catheters	Not Covered
0875T	Programming of subcutaneously implanted peritoneal ascites pump system by physician or other qualified health care professional	Not Covered
0876T	Duplex scan of hemodialysis fistula, computer-aided, limited (volume flow, diameter, and depth, including only body of fistula)	Not Covered
0877T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained without concurrent CT examination of any structure	Not Covered

	contained in previously acquired diagnostic imaging	
0878T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained with concurrent CT examination of the same structure	Not Covered
0879T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; radiological data preparation and transmission	Not Covered
0880T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; physician or other qualified health care professional interpretation and report	Not Covered
0881T	Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device	Not Covered
0882T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; initial nerve (List separately in addition to code for primary procedure)	Not Covered
0883T	Intraoperative therapeutic electrical stimulation of peripheral nerve to promote nerve regeneration, including lead placement and removal, upper extremity, minimum of 10 minutes; each additional nerve (List separately in addition to code for primary procedure)	Not Covered
0884T	Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed	Not Covered
0885T	Colonoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed	Not Covered

0886T	Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed	Not Covered
0887T	End-tidal control of inhaled anesthetic agents and oxygen to assist anesthesia care delivery (List separately in addition to code for primary procedure)	Not Covered
0888T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance	Not Covered
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation	Not Covered
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day	Not Covered
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	Not Covered
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day	Not Covered
0893T	Noninvasive assessment of blood oxygenation, gas exchange efficiency, and cardiorespiratory status, with physician or other qualified health care professional interpretation and report	Not Covered
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion	Not Covered

0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial 4 hours of monitoring time, including hourly physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment)	Not Covered
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (eg, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)	Not Covered
0897T	Noninvasive augmentative arrhythmia analysis derived from quantitative computational cardiac arrhythmia simulations, based on selected intervals of interest from 12-lead electrocardiogram and uploaded clinical parameters, including uploading clinical parameters with interpretation and report	Not Covered
0898T	Noninvasive prostate cancer estimation map, derived from augmentative analysis of image-guided fusion biopsy and pathology, including visualization of margin volume and location, with margin determination and physician interpretation and report	Not Covered
0899T	Noninvasive determination of absolute quantitation of myocardial blood flow (AQMBF), derived from augmentative algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	Not Covered
0900T	Noninvasive estimate of absolute quantitation of myocardial blood flow (AQMBF), derived from assistive algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	Not Covered

0901T	Placement of bone marrow sampling port, including imaging guidance when performed	Not Covered
0902T	QTc interval derived by augmentative algorithmic analysis of input from an external, patient-activated mobile ECG device	Not Covered
0903T	Electrocardiogram, algorithmically generated 12-lead ECG from a reduced-lead ECG; with interpretation and report	Not Covered
0904T	Electrocardiogram, algorithmically generated 12-lead ECG from a reduced-lead ECG; tracing only	Not Covered
0905T	Electrocardiogram, algorithmically generated 12-lead ECG from a reduced-lead ECG; interpretation and report only	Not Covered
0906T	Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; first application, total wound(s) surface area less than or equal to 50 sq cm	Not Covered
0907T	Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; each additional application, total wound(s) surface area less than or equal to 50 sq cm (List separately in addition to code for primary procedure)	Not Covered
0908T	Open implantation of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed	Not Covered
0909T	Replacement of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed	Not Covered
0910T	Removal of integrated neurostimulation system, vagus nerve	Not Covered
0911T	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; without programming by physician or other qualified health care professional	Not Covered
0912T	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; with simple programming by physician or other qualified health care professional	Not Covered
0913T	Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (eg, drug-coated, drug-eluting), including mechanical	Not Covered

	dilation by nondrug-delivery balloon angioplasty, endoluminal imaging using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) when performed, imaging supervision, interpretation, and report, single major coronary artery or branch	
0914T	Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (eg, drug-coated, drug-eluting) performed on a separate target lesion from the target lesion treated with balloon angioplasty, coronary stent placement or coronary atherectomy, including mechanical dilation by nondrug-delivery balloon angioplasty, endoluminal imaging using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) when performed, imaging supervision, interpretation, and report, single major coronary artery or branch (List separately in addition to code for percutaneous coronary stent or atherectomy intervention)	Not Covered
0915T	Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; pulse generator and dual transvenous electrodes/leads (pacing and defibrillation)	Not Covered
0916T	Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; pulse generator only	Not Covered
0917T	Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; single transvenous lead (pacing or defibrillation) only	Not Covered
0918T	Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; dual transvenous leads (pacing and defibrillation) only	Not Covered
0919T	Removal of a permanent cardiac contractility	Not Covered

	modulation-defibrillation system component(s); pulse generator only	
0920T	Removal of a permanent cardiac contractility modulation-defibrillation system component(s); single transvenous pacing lead only	Not Covered
0921T	Removal of a permanent cardiac contractility modulation-defibrillation system component(s); single transvenous defibrillation lead only	Not Covered
0922T	Removal of a permanent cardiac contractility modulation-defibrillation system component(s); dual (pacing and defibrillation) transvenous leads only	Not Covered
0923T	Removal and replacement of permanent cardiac contractility modulation-defibrillation pulse generator only	Not Covered
0924T	Repositioning of previously implanted cardiac contractility modulation-defibrillation transvenous electrode(s)/lead(s), including fluoroscopic guidance and programming of sensing and therapeutic parameters	Not Covered
0925T	Relocation of skin pocket for implanted cardiac contractility modulation-defibrillation pulse generator	Not Covered
0926T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation-defibrillation system	Not Covered
0927T	Interrogation device evaluation (in person) with analysis, review, and report, including connection, recording, and disconnection, per patient encounter, implantable cardiac contractility modulation-defibrillation system	Not Covered
0928T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation-defibrillation system with interim analysis and report(s) by a physician or other qualified health care professional	Not Covered
0929T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation-defibrillation system, remote data acquisition(s), receipt of transmissions, technician review, technical support, and distribution of results	Not Covered

0930T	Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), at time of initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator	Not Covered
0931T	Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), separate from initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator	Not Covered
0932T	Noninvasive detection of heart failure derived from augmentative analysis of an echocardiogram that demonstrated preserved ejection fraction, with interpretation and report by a physician or other qualified health care professional	Not Covered
0933T	Transcatheter implantation of wireless left atrial pressure sensor for long-term left atrial pressure monitoring, including sensor calibration and deployment, right heart catheterization, transseptal puncture, imaging guidance, and radiological supervision and interpretation	Not Covered
0934T	Remote monitoring of a wireless left atrial pressure sensor for up to 30 days, including data from daily uploads of left atrial pressure recordings, interpretation(s) and trend analysis, with adjustments to the diuretics plan, treatment paradigm thresholds, medications or lifestyle modifications, when performed, and report(s) by a physician or other qualified health care professional	Not Covered
0935T	Cystourethroscopy with renal pelvic sympathetic denervation, radiofrequency ablation, retrograde ureteral approach, including insertion of guide wire, selective placement of ureteral sheath(s) and multiple conformable electrodes, contrast injection(s), and fluoroscopy, bilateral	Not Covered
0936T	Photobiomodulation therapy of retina, single session	Not Covered
0937T	External electrocardiographic recording for greater	Not Covered

	than 15 days up to 30 days by continuous rhythm recording and storage; including recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional	
0938T	External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; recording (including connection and initial recording)	Not Covered
0939T	External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; scanning analysis with report	Not Covered
0940T	External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional	Not Covered
0941T	Cystourethroscopy, flexible; with insertion and expansion of prostatic urethral scaffold using integrated cystoscopic visualization	Not Covered
0942T	Cystourethroscopy, flexible; with removal and replacement of prostatic urethral scaffold	Not Covered
0943T	Cystourethroscopy, flexible; with removal of prostatic urethral scaffold	Not Covered
0944T	3D contour simulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation	Not Covered
0945T	Intraoperative assessment for abnormal (tumor) tissue, in-vivo, following partial mastectomy (eg, lumpectomy) using computer-aided fluorescence imaging (List separately in addition to code for primary procedure)	Not Covered
0946T	Orthopedic implant movement analysis using paired computed tomography (CT) examination of the target structure, including data acquisition, data preparation and transmission, interpretation and report (including CT scan of the joint or extremity performed with paired views)	Not Covered
0947T	Magnetic resonance image guided low intensity focused ultrasound (MRgFUS), stereotactic blood-brain barrier disruption using microbubble resonators to increase the concentration of	Not Covered

	blood-based biomarkers of target, intracranial, including stereotactic navigation and frame placement, when performed	
0948T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system with interim analysis, review and report(s) by a physician or other qualified health care professional	Not Covered
0949T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system, remote data acquisition(s), receipt of transmissions, technician review, technical support, and distribution of results	Not Covered
0950T	Ablation of benign prostate tissue, transrectal, with high intensity–focused ultrasound (HIFU), including ultrasound guidance	Not Covered
0951T	Totally implantable active middle ear hearing implant; initial placement, including mastoidectomy, placement of and attachment to sound processor	Not Covered
0952T	Totally implantable active middle ear hearing implant; revision or replacement, with mastoidectomy and replacement of sound processor	Not Covered
0953T	Totally implantable active middle ear hearing implant; revision or replacement, without mastoidectomy and replacement of sound processor	Not Covered
0954T	Totally implantable active middle ear hearing implant; replacement of sound processor only, with attachment to existing transducers	Not Covered
0955T	Totally implantable active middle ear hearing implant; removal, including removal of sound processor and all implant components	Not Covered
0956T	Partial craniectomy, channel creation, and tunneling of electrode for sub-scalp implantation of an electrode array, receiver, and telemetry unit for continuous bilateral electroencephalography monitoring system, including imaging guidance	Not Covered
0957T	Revision of sub-scalp implanted electrode array, receiver, and telemetry unit for electrode, when required, including imaging guidance	Not Covered
0958T	Removal of sub-scalp implanted electrode array,	Not Covered

	receiver, and telemetry unit for continuous bilateral electroencephalography monitoring system, including imaging guidance	
0959T	Removal or replacement of magnet from coil assembly that is connected to continuous bilateral electroencephalography monitoring system, including imaging guidance	Not Covered
0960T	Replacement of sub-scalp implanted electrode array, receiver, and telemetry unit with tunneling of electrode for continuous bilateral electroencephalography monitoring system, including imaging guidance	Not Covered
0961T	Shortwave infrared radiation imaging, surgical pathology specimen, to assist gross examination for lymph node localization in fibroadipose tissue, per specimen (List separately in addition to code for primary procedure)	Not Covered
0962T	Assistive algorithmic analysis of acoustic and electrocardiogram recording for detection of cardiac dysfunction (eg, reduced ejection fraction, cardiac murmurs, atrial fibrillation), with review and interpretation by a physician or other qualified health care professional	Not Covered
0963T	Anoscopy with directed submucosal injection of bulking agent into anal canal	Not Covered
0964T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; single arch, without mandibular advancement mechanism	Not Covered
0965T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, non-fixed hinge mechanism	Not Covered
0966T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, fixed hinge mechanism	Not Covered
0967T	Transanal insertion of endoluminal temporary colorectal anastomosis protection device, including vacuum anchoring component and flexible sheath connected to external vacuum source and	Not Covered

	monitoring system	
0968T	Insertion or replacement of epicranial neurostimulator system, including electrode array and pulse generator, with connection to electrode array	Not Covered
0969T	Removal of epicranial neurostimulator system	Not Covered
0970T	Ablation, benign breast tumor (eg, fibroadenoma), percutaneous, laser, including imaging guidance when performed, each tumor	Not Covered
0971T	Ablation, malignant breast tumor(s), percutaneous, laser, including imaging guidance when performed, unilateral	Not Covered
0972T	Assistive algorithmic classification of burn healing (ie, healing or nonhealing) by noninvasive multispectral imaging, including system set-up and acquisition, selection, and transmission of images, with automated generation of report	Not Covered
0973T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, trunk, arms, legs; first 100 sq cm	Not Covered
0974T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, trunk, arms, legs; each additional 100 sq cm (List separately in addition to code for primary procedure)	Not Covered
0975T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, scalp, neck, hands, feet, and/or multiple digits; first 100 sq cm	Not Covered
0976T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, scalp, neck, hands, feet, and/or multiple digits; each additional 100 sq cm (List separately in addition to code for primary procedure)	Not Covered
0977T	Upper gastrointestinal blood detection, sensor capsule, with interpretation and report	Not Covered

0978T	Submucosal cryolysis therapy; soft palate, base of tongue, and lingual tonsil	Not Covered
0979T	Submucosal cryolysis therapy; soft palate only	Not Covered
0980T	Submucosal cryolysis therapy; base of tongue and lingual tonsil only	Not Covered
0981T	Transcatheter implantation of wireless inferior vena cava sensor for long-term hemodynamic monitoring, including deployment of the sensor, radiological supervision and interpretation, right heart catheterization, and inferior vena cava venography, when performed	Not Covered
0982T	Remote monitoring of implantable inferior vena cava pressure sensor, physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial set-up and patient education on use of equipment	Not Covered
0983T	Remote monitoring of an implanted inferior vena cava sensor for up to 30 days, including at least weekly downloads of inferior vena cava area recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	Not Covered
0984T	Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure)	Not Covered
0985T	Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure)	Not Covered
0986T	Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure)	Not Covered

0987T	Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure)	Not Covered

Medical Evidence

Published recommendations or guidelines are not currently available from national societies and guidelines.

References

1. Centers for Medicare & Medicaid Services (CMS). Local coverage determination: Category III CPT codes (L35490). Revision Effective Date June 26, 2025.
<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35490&ver=81&bc=0>
2. Centers for Medicare & Medicaid Services (CMS). Billing and coding: Category III codes (A56902). Revision Effective Date January 1, 2025.
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56902&ver=47&bc=0>
3. American Medical Association (AMA). Criteria for CPT category I and category III codes. Updated September 22, 2023.
<https://www.ama-assn.org/practice-management/cpt/criteria-cpt-category-i-and-category-iii-codes>

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Cohere Medical Policy – Hysterectomy

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Medical Necessity Criteria

Service: Hysterectomy

Recommended Clinical Approach

Types of hysterectomy include supracervical (removal of uterus and the upper part of the cervix); total (removal of the entire uterus and the cervix); and radical (removal of the uterus, cervix, tissue on both sides of the cervix, and the upper part of the vagina). Procedures include vaginal, laparoscopic, laparoscopic-assisted vaginal, robotic, and abdominal hysterectomy. The route of hysterectomy depends on the size and shape of the vagina and uterus (including the ability to reach the uterus in cases of descensus or pelvic adhesions); the severity of extrauterine disease; and if a concurrent procedure is needed.¹

Medical Necessity Criteria

Indications

→ A **hysterectomy** is considered appropriate if **ANY** of the following is **TRUE**¹:

◆ **ANY** of the following symptoms:

- Abnormal uterine bleeding with **ALL** of the following⁴⁻⁵:
 - Unclear etiology after evaluation (e.g., hysteroscopy, imaging); **AND**
 - Therapies such as an intrauterine device (IUD), systemic hormonal therapy, tranexamic acid, or uterine-sparing procedures (e.g., endometrial ablation) are not indicated or have failed; **OR**
- Postpartum hemorrhage⁶; **OR**
- Other hemorrhages; **OR**
- Abnormal bleeding with uterine abnormality; **OR**
- Chronic pelvic pain with **ALL** of the following¹:
 - At least 6 months of persistent pain; **AND**
 - Symptoms do not improve with uterine-sparing therapy (e.g., progestins, oral contraceptives,

analgesics, gonadotropin-releasing hormone analogs, antidepressants, physical therapy); **OR**

◆ **ANY** of the following:

- Malignancy or premalignant disease with **ANY** of the following⁷:
 - Cervical cancer or adenocarcinoma in situ⁸; **OR**
 - Endometrial or other uterine cancer⁹; **OR**
 - Ovarian, fallopian tube, or primary peritoneal cancer¹⁰; **OR**
 - Endometrial intraepithelial neoplasia¹¹; **OR**
 - Cervical intraepithelial neoplasia (CIN)¹²; **OR**
 - Hereditary nonpolyposis colorectal cancer (HNPCC) or Lynch syndrome¹³; **OR**
 - For the prevention of **ANY** of the following¹⁴:
 - ◆ Malignant gestational trophoblastic disease¹⁵⁻¹⁶; **OR**
 - ◆ PTEN hamartoma tumor syndrome, Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome, Proteus syndrome or Proteus-like syndrome¹⁷; **OR**
 - ◆ Peutz-Jeghers syndrome¹⁸; **OR**
 - ◆ The patient is being referred for a bilateral oophorectomy for hormone receptor-positive breast cancer (HR+/HER2) and wants a concurrent hysterectomy¹⁹⁻²⁰; **OR**
 - ◆ The patient decides to have a hysterectomy in addition to a risk-reducing bilateral salpingo-oophorectomy (e.g., BRCA, BRIP1, PALB2, RAD51C, or RAD51D gene mutations)¹⁹⁻²⁰; **OR**
- Uterine leiomyoma and **ANY** of the following²¹⁻²²:
 - Abnormal uterine bleeding; **OR**
 - Iron-deficiency anemia; **OR**
 - Dyspareunia; **OR**
 - Fibroid is suspected to be malignant; **OR**
 - Pelvic pain or pressure; **OR**
 - Urinary or bowel dysfunction; **OR**

- Endometriosis with **ALL** of the following²³⁻²⁴:
 - Diagnosis confirmed by histology on biopsy, laparoscopic visualization, or identification of endometrioma on pelvic imaging; **AND**
 - Symptoms do not resolve with the use of (or patient cannot tolerate) progestins, gonadotropin-releasing hormone analogs, or uterine-sparing therapies (e.g., destruction of implants, removal of endometrioma, lysis of adhesions); **OR**
- Pelvic inflammatory disease (PID)²⁵; **OR**
- Pelvic organ prolapse and **ALL** of the following are **TRUE**²⁶⁻²⁸:
 - Symptomatic with **ANY** of the following:
 - ◆ Defecatory dysfunction (e.g., incomplete emptying, constipation, incontinence, pain); **OR**
 - ◆ Voiding dysfunction (e.g., incomplete emptying, difficulty urinating, incontinence, recurrent infection); **OR**
 - ◆ Physical activity limitations; **OR**
 - ◆ Discomfort (e.g., pressure, pain); **OR**
 - ◆ Sexual dysfunction due to prolapse (dyspareunia); **OR**
 - ◆ Vaginal bulge or visible prolapse; **AND**
 - Symptoms do not improve with the use of (or the patient cannot tolerate) **ANY** of the following:
 - ◆ Pessary; **OR**
 - ◆ Pelvic floor muscle training; **OR**
 - ◆ Other non-invasive measures.

Non-Indications

→ A **hysterectomy** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ When surgery is not safe or beneficial to the patient; **OR**
- ◆ For the treatment of premenstrual syndrome (PMS) or premenstrual dysphoric disorder (PDD).

Level of Service Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58152	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s); with colpo-urethrocystopexy (e.g., Marshall-Marchetti-Krantz, Burch)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58200	Total abdominal hysterectomy, including partial vaginectomy, with para-aortic and pelvic lymph node sampling, with or without removal of tube(s), with or without removal of ovary(s)
58210	Radical abdominal hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele
58267	Vaginal hysterectomy, for uterus 250 g or less; with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele
58275	Vaginal hysterectomy, with total or partial vaginectomy

58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58548	Laparoscopy, surgical, with radical hysterectomy, with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy), with removal of tube(s) and ovary(s), if performed
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or

	ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58575	Laparoscopy, surgical, total hysterectomy for resection of malignancy (tumor debulking), with omentectomy including salpingo-oophorectomy, unilateral or bilateral, when performed
58951	Resection (initial) of ovarian, tubal or primary peritoneal malignancy with bilateral salpingo-oophorectomy and omentectomy; with total abdominal hysterectomy, pelvic and limited para-aortic lymphadenectomy
58953	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking
58954	Bilateral salpingo-oophorectomy with omentectomy, total abdominal hysterectomy and radical dissection for debulking; with pelvic lymphadenectomy and limited para-aortic lymphadenectomy
58956	Bilateral salpingo-oophorectomy with total omentectomy, total abdominal hysterectomy for malignancy
59525	Subtotal or total hysterectomy after cesarean delivery (List separately in addition to code for primary procedure)

Medical Evidence

Hassan et al. (2023) provided an update to a previous systematic review on "the long-term outcomes of bilateral salpingo-oophorectomy (BSO) at the time of hysterectomy." A meta-analysis of studies included women who had surgery compared to those who did not. Breast cancer risk decreased in young women who had a hysterectomy with BSO; however, there was an increase in colorectal cancer. Stroke, as well as cardiovascular and coronary heart disease, were also reported in the group. Patients who did not have surgery before age 50 have an increased risk of hyperlipidemia, diabetes, hypertension, dementia, and depression.³⁰

Alkatout et al. (2023) conducted a review (35 studies) on the outcomes following total or subtotal hysterectomy for patients with endometriosis or adenomyosis. Findings show that endometriosis may reoccur regardless of the type of procedure and additional treatment may be needed. The authors reported no significant differences between the two types of procedures with respect to recurrence of disease, sexual function, quality of life, and overall patient satisfaction. The authors note the need for randomized control trials (RCTs) in these areas.³¹

Lee et al. (2019) analyzed RCTs concerning operation time, postoperative pain, and surgical complications of laparoscopic and vaginal hysterectomies. Data from 18 studies (n=1618) find that vaginal hysterectomy is the preference for benign indications. The procedure reports improved postoperative pain scores at 24 hours compared to laparoscopic hysterectomy and reduced surgical time. The authors did not identify significant differences regarding the length of hospital stay or return to regular activity.³²

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Clinical Guideline Revision History/Information

Original Date: August 23, 2023		
Review History		
Version 2	2/13/2025	• Annual review. • Added a non-indication, "For the treatment of premenstrual syndrome (PMS) or premenstrual dysphoric disorder (PDD)". • Literature review completed; no new studies identified.



Cohere Medical Policy – Hysteroscopy

Clinical Guidelines for Medical Necessity Review

Version: 2
Revision Date: February 20, 2025

Important Notices

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Medical Necessity Criteria

Service: Hysteroscopy

Recommended Clinical Approach

Hysteroscopy allows for the examination of the inside of the uterus to diagnose infertility and causes of abnormal uterine bleeding. The minimally invasive procedure is also used to remove fibroids and polyps. The timing of the procedure is usually dependent upon a woman's menstrual cycle. For premenopausal women, diagnostic hysteroscopy is typically recommended during the follicular phase of the menstrual cycle following menstruation. The procedure is recommended at any time for women with menses that are not on a regular cycle; the procedure should not be performed during active menses as visualization will be limited.¹

Medical Necessity Criteria

Indications

→ **Hysteroscopy** is considered appropriate if **ANY** of the following is **TRUE**:

◆ Evaluation of **ANY** of the following:

- Malignancy, including biopsy¹⁻²; **OR**
- Abnormal bleeding with **ANY** of the following³:
 - Premenopausal bleeding with **ANY** of the following⁴:
 - ◆ Anemia; **OR**
 - ◆ Blind endometrial sampling that is non-diagnostic or inadequate⁵; **OR**
 - ◆ The patient has a high-risk of endometrial cancer based on **ANY** of the following^{3,5-7}:
 - Age 45 years or older⁸; **OR**
 - Diabetes; **OR**
 - Early age at menarche; **OR**
 - Family history of endometrial or colon cancer; **OR**

- Long-term unopposed estrogen therapy⁸; **OR**
- Lynch syndrome; **OR**
- Nulliparity; **OR**
- Obesity; **OR**
- Polycystic ovary syndrome; **OR**
- Tamoxifen use; **OR**
- ◆ Medical treatment (e.g., hormone therapy) does not successfully treat heavy bleeding⁹; **OR**
- ◆ Continuous hormone therapy with vaginal bleeding that continues after 6 months; **OR**
- ◆ Uterine structural abnormalities as evidenced by **ANY** of the following:
 - Cesarean scar defect^{1,10}; **OR**
 - Congenital uterine anomaly; **OR**
 - Endometrial polyps¹¹; **OR**
 - Leiomyoma¹²⁻¹³; **OR**
- Postmenopausal bleeding with **ANY** of the following¹⁴:
 - ◆ Cyclical hormone treatment with unexpected vaginal bleeding; **OR**
 - ◆ High-risk of endometrial cancer with **ANY** of the following^{3,5-7}:
 - Age 45 years or older⁸; **OR**
 - Diabetes; **OR**
 - Early age at menarche; **OR**
 - Family history of endometrial or colon cancer; **OR**
 - Menopause after age 55¹⁵⁻¹⁶; **OR**
 - Long-term unopposed estrogen therapy⁸; **OR**
 - Lynch syndrome; **OR**
 - Nulliparity; **OR**
 - Obesity; **OR**
 - Polycystic ovary syndrome; **OR**

- Tamoxifen use; **OR**
 - ◆ Blind endometrial sampling that is non-diagnostic or inadequate⁵; **OR**
 - ◆ Endometrium thickness of 4mm or more as evidenced by transvaginal ultrasound¹⁷; **OR**
 - ◆ Polyp or other intracavitary lesions as evidenced by transvaginal ultrasound or sonohysterography¹⁷; **OR**
- Chronic pelvic pain with evaluation is required as evidenced by **ALL** of the following:
 - Pain with a duration of 6 months or more; **AND**
 - Transvaginal ultrasound inconclusive; **OR**
- Endometrial evaluation has been completed, and ablation is indicated as evidenced by **ALL** of the following^{9,18}:
 - Absence of endometrial hyperplasia or uterine cancer on endometrial sampling; **AND**
 - Childbearing is no longer desired; **AND**
 - The shape of the uterus is normal (e.g., no septums or uterine anomalies); **AND**
 - Premenopausal bleeding and **ANY** of the following:
 - ◆ Anemia; **OR**
 - ◆ Medical treatment (e.g., hormone therapy) does not successfully treat heavy bleeding; **OR**
- The patient has **ALL** of the following¹⁹⁻²⁰:
 - **ANY** of the following:
 - ◆ Under the age of 35 and is unable to conceive following 1 year or more of unprotected sexual intercourse²¹; **OR**
 - ◆ Over the age of 35 and is unable to conceive following 6 months or more of unprotected sexual intercourse²¹; **AND**
 - **ANY** of the following:
 - ◆ Two or more failed clinical pregnancies prior to 20 weeks of gestation²⁰; **OR**

- ◆ Two or more failed in vitro fertilization cycles²²;
OR
- ◆ Uterine structural abnormalities with **ANY** of the following^{20,23}:
 - Endometrial polyps²⁴; **OR**
 - Unable to conceive after 1 year or more of unprotected sexual intercourse (if under the age of 35) or after 6 months of trying (if over the age of 35) following prior cesarean birth (e.g., cesarean-induced isthmocele)^{1,25}; **OR**
 - Leiomyoma²⁴; **OR**
 - Uterine anomaly²⁶; **OR**
- ◆ **ANY** of the following procedures are indicated with hysteroscopy:
 - Lysis of intrauterine adhesions (Asherman syndrome)^{20,27};
OR
 - Endometrial ablation; **OR**
 - Bilateral fallopian tube cannulation¹; **OR**
 - Division or resection of intravaginal/intrauterine septum when **ANY** of the following is **TRUE**²⁸⁻²⁹:
 - Presence of vaginal septum on examination; **OR**
 - Advanced imaging (e.g., hysterosalpingogram, sonohysterography, magnetic resonance imaging [MRI]) confirms the presence of a uterine septum³⁰;
OR
 - Removal of leiomyomata when **ALL** of the following are **TRUE**¹²⁻¹³:
 - Presence of a leiomyoma with **ANY** of the following:
 - ◆ Infertility^{24,30}; **OR**
 - ◆ Recurrent pregnancy loss²⁰; **OR**
 - ◆ Abnormal uterine bleeding that does not resolve with conservative treatment (e.g., hormonal therapy, NSAIDs); **OR**
 - Imaging or diagnostic hysteroscopy confirms the presence of submucosal leiomyomas²⁰; **OR**

- Removal of foreign bodies (e.g., intrauterine devices with non-visualized strings or intrauterine devices that are malpositioned).¹

Non-Indications

→ **Hysteroscopy** is not considered appropriate if **ANY** of the following is **TRUE**¹:

- ◆ Pregnancy; **OR**
- ◆ Active pelvic infection; **OR**
- ◆ Women with prodromal or active herpes infection.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
58555	Hysteroscopy, diagnostic (separate procedure)
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C
58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method)
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)
58561	Hysteroscopy, surgical; with removal of leiomyomata
58562	Hysteroscopy, surgical; with removal of impacted foreign body
58563	Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
58579	Unlisted hysteroscopy procedure, uterus

G9823	Endometrial sampling or hysteroscopy with biopsy and results documented during the 12 months prior to the index date (exclusive of the index date) of the endometrial ablation
G9824	Endometrial sampling or hysteroscopy with biopsy and results not documented during the 12 months prior to the index date (exclusive of the index date) of the endometrial ablation

Medical Evidence

Vitale et al. (2023) performed a systematic review and meta-analysis on the efficacy of hysteroscopy to improve infertility outcomes. Fifteen studies were included with 5038 women who underwent an assisted reproductive technique (ART). Moderate-quality evidence demonstrated that hysteroscopy increased live birth rate (LBR) (relative risk [RR] 1.24, 95% confidence interval [CI] 1.09–1.43, I² = 21%) and clinical pregnancy (CPR) (RR 1.36, 95% CI: 1.18–1.57; I² = 51%). In addition, hysteroscopy may increase CPR for the treatment of intrauterine pathologies (RR 2.13, 95% CI: 1.56–2.92, I² = 0%) however, the authors note that studies included low-quality data.^{[31](#)}

Roig et al. (2023) conducted a systematic review and meta-analysis on the efficacy of diagnostic hysteroscopy prior to an initial in vitro fertilization (IVF) cycle on CPR and LBR. A total of 5056 patients in 12 studies were included (6 randomized controlled trials, 1 prospective cohort study, 3 retrospective cohort studies, and 2 case-control studies). Evidence shows that routine hysteroscopy prior to an initial IVF procedure can increase CPR (odds ratio [OR], 1.49; 95% confidence CI 1.16–1.91; I² = 69%) while LBR is not affected.^{[32](#)}

Bosteels et al. (2018) performed a meta-analysis on the efficacy of hysteroscopy for women with unexplained infertility. The procedure was indicated for women with endometrial polyps, submucous fibroids, uterine septum, or intrauterine adhesions. Hysteroscopy improved outcomes. However, the authors note the need for additional research to study the rates of pregnancy among women with unexplained subfertility and submucous fibroids.^{[24](#)}

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Clinical Guideline Revision History/Information

Original Date: October 27, 2023		
Review History		
Version 2	2/20/2025	• Annual review. • On pp. 6-7, reorganized indication regarding infertility: ○ Removed the indication, “to investigate a foreign body”; ○ Grouped 2 bullets (“under the age of 35 and is unable to conceive following 1 year or more of unprotected sexual intercourse” and “over the age of 35 and is unable to conceive following 6 months or more of unprotected sexual intercourse”); ○ Grouped 3 bullets (“two or more failed clinical pregnancies prior to 20 weeks of gestation”, “two or more failed in vitro fertilization cycles”, and “uterine structural abnormalities” which includes 4 sub-bullets [endometrial polyps, unable to conceive, leiomyoma, or uterine anomaly])). • Added 3 new references: ○ National Cancer Institute (NCI), 2024; ○ American Cancer Society (ACS), 2019; ○ American College of Obstetricians and Gynecologists (ACOG) (2022).



Cohere Medical Policy – Breast Cancer Genetic Testing

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Laboratory Tests

Policy Name: Cohere Medical Policy - Breast Cancer Genetic Testing

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Breast Cancer Genetic Testing

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation

demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Description

Genetic testing for hereditary breast cancer includes several single gene or multi-panel tests to evaluate whether a patient has a genetic variant associated with an elevated risk of developing certain cancers, predict clinical outcomes after a cancer diagnosis, or predict likely responses to treatment.¹ These tests are typically performed following risk assessment using established clinical tools and in collaboration with a certified genetic counselor.² The identification of high penetrance genes (e.g., BRCA1, BRCA2, PALB2, TP53, PTEN, STK11, CDH1) can help guide treatment decisions, including surgery, chemotherapy, biologics, and radiation. Testing can also help estimate the risks of second primary cancers.³ For example, carriers of pathogenic BRCA variants have an elevated risk of developing a second primary breast cancer and may consider bilateral mastectomy over lumpectomy or unilateral/subtotal mastectomy.⁴⁻⁷ While germline genetic testing provides insight into inherited cancer susceptibility through identification of pathogenic variants, gene expression profiling (GEP) analyzes patterns of gene expression in tumor tissue. GEP can be used to predict recurrence risk and guide treatment decisions, particularly the use of chemotherapy.⁸

Medical Necessity Criteria

Indications

Breast cancer genetic testing is considered appropriate if **ANY** of the following is **TRUE**:

- Genetic testing for hereditary breast cancer (single or multi-gene) for **ANY** of the following:
 - Newly diagnosed or with a personal history of breast cancer^{2,6}; **OR**
 - Personal history of **ANY** of the following other cancers⁹:
 - Ovarian cancer (including fallopian tube or primary peritoneal cancer)³; **OR**
 - Pancreatic cancer; **OR**
 - Prostate cancer with **ANY** of the following:
 - Metastatic (Stage IVB) or node-positive (Stage IVA) prostate cancer; **OR**
 - Very high-risk or high-risk disease; **OR**
 - Ashkenazi Jewish ancestry; **OR**
 - **ANY** of the following in the family history:
 - At least one close blood relative^A with **ANY** of the following:
 - Breast cancer at less than or equal to 50 years of age; **OR**
 - Male breast cancer; **OR**
 - Metastatic, node-positive, very high-risk, or high-risk prostate cancer; **OR**
 - Ovarian cancer; **OR**
 - Pancreatic cancer; **OR**
 - At least two close blood relatives on the same side of the family with **ANY** of the following:
 - Breast cancer; **OR**
 - Prostate cancer (any grade); **OR**
 - Family history including **ANY** of the following⁹:
 - Patient is unaffected and **ALL** of the following:
 - First or second-degree blood relative^A with a history of **ANY** of the following cancers:
 - Breast; **OR**
 - Ovarian; **OR**
 - Pancreatic; **OR**
 - Prostate cancer with any other qualifying risk factor^B; **AND**

- Patient is greater than or equal to 18 years of age¹⁰; **AND**
- **ANY** of the following:
 - Affected family member not available for testing; **OR**
 - Relative required testing for more than systemic therapy decision-making; **OR**
 - Greater than or equal to 18 years of age with a probability of greater than or equal to 5% of a BRCA1/2P/LP variant based on prior probability models (e.g., Tyrer-Cuzick, BRCAPro, CanRisk)¹¹; **OR**
- Gene expression profiling (GEP) with **ALL** of the following^{12,13}:
 - To guide decisions for adjuvant chemotherapy or endocrine therapy; **AND**
 - HER2 negative; **AND**
 - Hormone receptor-positive; **AND**
 - Tumor greater than or equal to 0.5 cm; **AND**
 - **ANY** of the following:
 - Node-negative; **OR**
 - One to three positive nodes; **OR**
 - Axillary-node micrometastasis less than or equal to 2.0 mm; **OR**
- Gene expression profiling (GEP) for ductal carcinoma in situ (DCIS) with **ALL** of the following^{5,14,15-17}:
 - Excisional or core biopsy pathology demonstrates DCIS of the breast; **AND**
 - No pathological evidence of invasive disease; **AND**
 - Formalin-fixed paraffin-embedded (FFPE) specimen has at least 0.5 mm of DCIS length; **AND**
 - Candidate for **ANY** of the following:
 - Breast-conserving surgery; **OR**
 - Breast-conserving surgery with adjuvant radiation therapy.

Non-Indications

Breast cancer genetic testing is not considered appropriate if **ANY** of the following is **TRUE**:

- Genetic testing for hereditary breast cancer (single or multi-gene) for patients without a personal or family history associated with potentially pathogenic BRCA1/2 gene mutations¹⁸; **OR**
- Direct-to-consumer testing for any indication; **OR**
- Gene expression profiling for **ANY** of the following¹³:

- Gene expression profiling for ductal carcinoma in situ (DCIS) when a mastectomy is planned; **OR**
- HER2-positive breast cancer; **OR**
- Metastatic or locally advanced breast cancer with four or more positive nodes; **OR**
- Triple-negative breast cancer.

Definitions and Notes

^AClose blood relative: The National Comprehensive Cancer Network (NCCN) defines a close blood relative as a first-, second-, or third-degree relative on the same side of the family. First-degree relatives include children, full-siblings, and parents. Second-degree relatives include aunts, uncles, grandchildren, grandparents, nephews, nieces, and half-siblings. Third-degree relatives include first cousins, great-aunts and great-uncles, great-grandchildren and great-grandparents, half-aunts and half-uncles.^{9,11}

^BQualifying risk factors for family history of prostate cancer: The patient qualifies for testing if a first or second degree relative with prostate cancer has at least one additional factor from the list below:

- Metastatic (Stage IVB) or node-positive (Stage IVA) prostate cancer.
- Very high-risk or high-risk disease.
- Ashkenazi Jewish ancestry.
- Family history (close blood relative) of: breast cancer at less than or equal to 50 years of age; male breast cancer; ovarian cancer; pancreatic cancer; metastatic, node-positive, very high-risk, or high-risk prostate cancer.
- At least two close blood relatives on the same side of the family with prostate (any grade) or breast cancer.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (ie, detection of large gene rearrangements)
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81212	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants

81215	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
81307	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence
81308	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; known familial variant
81309	PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20)
81432	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer, hereditary pancreatic cancer, hereditary prostate cancer), genomic sequence analysis panel, 5 or more genes, interrogation for sequence variants and copy number variants
81433	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11
81519	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as

	recurrence score
81520	Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score
81521	Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis
81522	Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score
81523	Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis
0045U	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score

Medical Evidence

Germline Genetic Testing

Yadav et al. (2020) compared the relative performance of the National Comprehensive Cancer Network (NCCN) genetic testing criteria against the American Society of Breast Surgeons recommendation to test all patients aged 65 years and younger diagnosed with breast cancer. In a cohort of 3907 breast cancer patients, the authors compared the ability of the two approaches to detect pathogenic variants in 9 predisposition genes (ATM, BRCA1, BRCA2, CDH1, CHEK2, NF1, PALB2, PTEN, TP53). The authors evaluated both sensitivity (the proportion of patients who met criteria and tested positive for pathogenic variants) and specificity (the proportion of patients who did not meet testing criteria and tested negative for pathogenic variants). They reported that the NCCN criteria had 87% sensitivity and 53.5% specificity for detecting pathogenic variants in BRCA1/BRCA2. The American Society of Breast Surgeons' recommendation for genetic testing of all breast cancer patients under 65 resulted in a 98% sensitivity and 22% specificity to detect BRCA1/BRCA2 carriers. The authors concluded that expanding the testing criteria to include all breast cancer patients under the age of 65 years can substantially improve the detection of pathogenic germline mutations. While this broader approach, with its lower specificity, may increase costs, the authors noted that the cost of genetic testing continues to decline as technologies advance.¹⁹

Beitsch et al. (2019) reported the results of a multicenter prospective registry study of 959 current or previous breast cancer patients who underwent an 80-gene panel test. The authors reported that 49.95% of patients met NCCN clinical criteria, of whom 9.39% had a pathogenic or likely pathogenic variant. Among patients who did not meet NCCN clinical criteria, 7.9% had a pathogenic or likely pathogenic variant, a difference that did not reach statistical significance. The authors concluded that NCCN guidelines may fail to identify pathogenic or likely pathogenic mutations in approximately half of breast cancer patients.²⁰

Cropper et al. (2017) conducted a retrospective chart review of 1123 patients with breast cancer to evaluate the performance of 14 NCCN clinical criteria in

identifying BRCA1 and BRCA2 mutation carriers. The authors reported that 88.9% of BRCA1/BRCA2 mutation carriers met at least one NCCN criterion. Notably, the likelihood of detecting a mutation was substantially higher among patients who met multiple criteria, whereas those who met only one criterion had mutation rates similar to unselected breast cancer populations. The authors concluded that patients meeting two or more NCCN criteria had high rates of BRCA1/BRCA2 mutations, whereas patients who met only one criterion had rates comparable to unselected breast cancer patients.²¹

Gene expression profiling

Berton Giachetti et al. (2025) reviewed the use of the Oncotype DX genomic assay in the management of early breast cancer. Oncotype DX is a quantitative real-time polymerase chain reaction (qRT-PCR)-based 21-gene recurrence score assay comprising 16 cancer-related genes and 5 reference genes. It is used to identify patients with hormone receptor-positive and HER2-negative early breast cancer who may safely forgo adjuvant chemotherapy. The assay generates a recurrence score between 0 and 100, corresponding to the risk of disease recurrence. The authors summarized clinical trial results showing that, among patients with recurrence scores less than 25, chemotherapy did not improve invasive disease-free survival at 5 years, supporting the test's predictive value in guiding treatment decisions. However, the authors also noted evidence from other trials suggesting that patients younger than 50 years with recurrence scores under 25 may still derive benefit from chemotherapy, potentially due to the anti-estrogenic effects of chemotherapy-induced premature menopause. The authors concluded that the OnctypeDX test has established clinical validity, though it should be used in conjunction with clinician and genetic counselor guidance.⁸

Guidelines

The most recent National Comprehensive Cancer Network (NCCN) guidelines for genetic/familial high-risk assessment of breast, ovarian, pancreatic, and prostate cancer contain several testing criteria for high-penetrance breast cancer susceptibility genes (e.g., BRCA1, BRCA2, CDH1, PALB2, PTEN, STK11, TP53). The guidelines recommend testing for any patient under the age of 50 years with a personal history of breast cancer. For patients of any age, the guidelines recommend testing for five broad categories: to aid in systemic or adjuvant treatment decisions, in cases of specific pathology, for all male

breast cancer patients, for all patients with Ashkenazi Jewish ancestry, and for patients with specific family cancer histories. The guidelines also include criteria for evaluating patients with ovarian, prostate, and pancreatic cancer for hereditary cancer susceptibility genes, many of which overlap with breast cancer susceptibility genes (e.g., BRCA1, BRCA2, and PALB2 for ovarian cancer; BRCA1, BRCA2, PALB2, STK11, and TP53 for pancreatic cancer; and BRCA1, BRCA2, PALB2, and TP53 for prostate cancer).⁹

The NCCN guidelines on breast cancer contain several recommendations for gene expression profiling (GEP) to guide treatment decisions. The guidelines suggest that 21-gene RT-PCR assays be administered to patients with HR-positive, HER2-negative disease who are candidates for chemotherapy. The guidelines further note an absence of evidence for the utility of GEP in patients with 4 or more nodes.¹³

The American College of Obstetricians and Gynecologists (ACOG) practice bulletin on hereditary breast and ovarian cancer syndrome notes that germline mutations in the BRCA1 and BRCA2 genes account for both breast and ovarian cancer. The practice bulletin thus recommends genetic counseling for all patients diagnosed with ovarian cancer. Genetic testing is recommended when the risk assessment performed as part of the genetic counseling suggests an inherited cancer syndrome and when test results are likely to influence medical management, which may include risk-reducing combined hormonal contraceptive use and risk-reducing surgeries, including mastectomy, oophorectomy, and salpingectomy.³

The United States Preventive Services Task Force (USPSTF) recommendation statement on risk assessment, genetic counseling, and genetic testing for BRCA-related cancer recommends that “primary care clinicians assess women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or who have an ancestry associated with breast cancer susceptibility 1 and 2 (BRCA1/2) gene mutations with an appropriate brief familial risk assessment tool”. The USPSTF does not recommend routine risk assessment, genetic counseling, or genetic testing for women whose personal or family history/ancestry is not associated with BRCA1/2 mutations (D recommendation).¹⁸

Manahan et al. (2019) outlined consensus guidelines published by the American Society of Breast Surgeons (ASBS), including the following^{2,5}:

- Medical professionals knowledgeable in genetic testing (e.g., breast surgeons and genetic counselors) should provide patient education, counseling, and testing recommendations. However, there is no consensus on which genes should be tested in various clinical scenarios.
- All patients with a personal history of breast cancer should be offered testing, including BRCA1/2 and PALB2 mutations. Treatment recommendations could be enhanced by testing.
- Patients who have previously undergone genetic testing may benefit from updated testing, particularly if performed before 2014, as PALB2 testing was not available at that time.
- Patients who meet NCCN guidelines who do not have a personal history of breast cancer should be tested unless an affected relative is available for testing, which is preferred.
- When variants of uncertain significance are found, no clinical action is needed. Patients should be managed based on risk factors, not on these inconclusive results.

Hampel et al. (2014) published a practice guideline from the American College of Medical Genetics and Genomics and the National Society of Genetic Counselors. A referral for breast cancer genetic testing consultation is recommended for females and males. Additional recommendations generally mirror NCCN guidelines.¹⁴

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Version 2	04/09/2026	Annual review. Updated CPT code descriptions in accordance with 01/01/2026 AMA update. Broadened indication for all patients with newly diagnosed or with a history of breast cancer in accordance with recommendations of the American Society of Breast Surgeons. Added indications for patients with a personal history of other related cancers. Edited family history criteria for clarity and usability. Added definitions (Close blood relative and Qualifying risk factors for family history of prostate cancer). Reorganized and edited Medical Evidence including 4 additional references.



Cohere Medicare Advantage Policy – Diaphragmatic/Phrenic Nerve Electrical Stimulators

Clinical Guidelines for Medical Necessity Review

Version: 1
Revision Date: March 13, 2025

Important Notices

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Guideline Information:

Specialty Area: Sleep Medicine

Guideline Name: Cohere Medicare Advantage Policy - Diaphragmatic/Phrenic Nerve Electrical Stimulators

Date of last literature review: 03/12/2025

Document last updated: 03/12/2025

Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Diaphragmatic/Phrenic Nerve Electrical Stimulators

Benefit Category

Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [National Coverage Determination \(NCD\). Phrenic Nerve Stimulator \(160.19\)](#)

Recommended Clinical Approach

The phrenic nerve controls the movement of the diaphragm to facilitate respiration by allowing air to move into the lungs. Electrical stimulation of the phrenic nerve may be achieved by the implantation of a device that can detect cessation of breathing and trigger contraction of the diaphragm to simulate natural respiration. These devices have been used for short-term daily respite from mechanical ventilation in patients with high-level (C3 and higher) spinal cord injuries (SCI) as well as conditions affecting respiration such as central alveolar hypoventilation syndrome.²⁻³ Clinical studies are ongoing related to proposed use in central sleep apnea (CSA), amyotrophic lateral sclerosis (ALS), and difficult-to-wean mechanically ventilated individuals.⁴⁻⁷

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of diaphragmatic/phrenic nerve electrical stimulators. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting

incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- If the patient does not have an intact diaphragm and phrenic nerve, an implanted phrenic nerve stimulator will not be effective.¹
- The stimulator may not work if there is nerve injury to the patient during the implantation procedure.¹
- The device may not be effective for the patient, which could result in the patient returning to full-time mechanical ventilation for survival.¹
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Diaphragmatic/phrenic nerve electrical stimulation has been used for several conditions that have resulted in hypoventilation including spinal cord and brain stem injuries.¹
- Potential for temporary daily ventilator weaning (approximately 4 hours/day) which can improve quality of life for patients who require invasive or noninvasive mechanical ventilation.¹
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **Diaphragmatic/phrenic nerve electrical stimulation** is considered appropriate if **ALL** of the following are **TRUE**^{1, 2-3, 8}:
- ◆ The patient has an intact diaphragm and phrenic nerve; **AND**
 - ◆ Partial or complete respiratory insufficiency is present; **AND**
 - ◆ Intermittent or permanent use of a mechanical ventilator is required.

Non-Indications

- **Diaphragmatic/phrenic nerve electrical stimulation** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Central sleep apnea (e.g, remedē)^{4, 9-11}; **OR**
 - ◆ Amyotrophic lateral sclerosis (ALS)^{5,12}; **OR**
 - ◆ Temporary respiratory insufficiency or difficult-to-wean patients on mechanical ventilation^{6,13}; **OR**
 - ◆ Denervation of the diaphragm.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
33277	Insertion of phrenic nerve stimulator transvenous sensing lead (List separately in addition to code for primary procedure)
33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed;

	system, including pulse generator and lead(s)
33279	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only
33280	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)
33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator
93150	Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming
93151	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
93153	Interrogation without programming of implanted phrenic nerve stimulator system

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Romero et al. (2012) completed a retrospective cohort study of cervical spinal cord injury (SCI) patients on permanent respiratory support. Potential for improved health-related quality of life (HRQL), long-term tolerability, and improved patient survival were indicators of effectiveness of the device. Of the 126 study participants, 38 patients received phrenic nerve stimulation (pacing) and 88 were mechanically ventilated. Patients included were those with high cervical SCI requiring volumetric mechanical ventilatory support from the moment of injury and exclusion criteria included active pulmonary infections, cancer, or other terminal illness. Mental disability and lack of family or caregiver support were not considered exclusions from the study. It was concluded that phrenic nerve stimulation, particularly in those younger members of the implant group, can impact long-term survival in patients with ventilator-dependent high SCI, with improved HRQL.¹⁴

Ataya and colleagues (2020) conducted the US-based RESCUE 1, multicenter, prospective open-label single treatment group feasibility study of adult patients. These were mechanical ventilation-dependent patients who had failed at least two weaning trials and who received temporary transvenous diaphragmatic neurostimulation (TTDN) in conjunction with the standard of care. Patients in this study were adults 18 years of age or older and medically stable, having been on mechanical ventilation for at least 7 days. Hypovolemia, neuromuscular disorder, known or suspected phrenic nerve paralysis, terminal illness, or body mass index greater than or equal to 40 were among the study exclusion criteria. The study number was small with 14 patients, 11 who remained throughout the study and 7 who received the TTDN treatment. Two patients were unable to have the device placed due to inability to thread the guidewire due to potential anatomical barriers. The overall conclusion was that TTDN is safe and feasible in patients who are difficult to wean from mechanical ventilation. Future studies with greater numbers of participants are recommended.¹³

The RESCUE II study results were presented by Dres et al. (2021) in the American Journal of Respiratory Critical Care Medicine (American Thoracic Society). The randomized, controlled, multi-center, open-label study focused

upon patients 18 years of age or older on mechanical ventilation for greater than or equal to 4 days, having failed at least 2 weaning attempts. There were 127 eligible participants, with 112 randomized to 57 in the treatment group with temporary transvenous diaphragm neurostimulation (TTDN) and 55 in the control group. It was concluded that TTDN combined with standard management did not increase the proportion of successful weaning from mechanical ventilation when compared to solely standard treatment. Further studies were recommended.⁶

The American Academy of Sleep Medicine (AASM) maintains a 2012 guideline (Aurora et al.) for treatment of central sleep apnea with practice parameters. The literature review and meta-analyses do not reference diaphragmatic/phrenic nerve stimulation for central sleep apnea treatment and no recommendations located on this society's website currently support the use of the device.¹¹

Sagalow et al. (2022) conducted a systematic review published in the American Journal of Cardiology regarding transvenous phrenic nerve stimulation of central sleep apnea. There were 232 patients in the studies examined who were implanted with the device. While the device was found overall to be of benefit to patients, there were multiple limitations, including that the device is only active at night when patients are lying supine. CSA is present both at nighttime and in the daytime in heart failure patients in the form of Cheyne-Stokes respirations. This is indicative of a more serious prognosis. Patients with significant heart failure are unable to lie in a supine position due to orthopnea. A meta-analysis was unable to be completed due to a lack of consistent outcome measures in the articles. The authors recommend additional studies in the future focusing on long-term outcomes and complications which would be independent from the initial clinical trial results.⁴

A 2019 publication in The American Journal of Respiratory and Critical Care Medicine (Guimarães-Costa et al.) reviews findings of two clinical trials: DiPALS (Diaphragm Pacing in Patients with Amyotrophic Lateral Sclerosis) and RespiStimALS (Early Diaphragm Pacing in Patients with Amyotrophic Lateral Sclerosis). A diaphragm biopsy substudy of the RespiStimALS protocol was conducted on 39 patients, with 19 of these patients having left diaphragm

electrical activity recording. Two of the 19 patients were eventually excluded with a resulting 17 patients (active stimulation in 8 patients and sham in 9) with electrophysiological recordings for analysis. Through this mechanistic evaluation, it was concluded that electrical stimulation delays reinnervation of denervated muscle fibers in the diaphragm with resulting harmful effect.¹²

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Clinical Guideline Revision History/Information

Original Date: March 13, 2025		
Review History		



Cohere Medicare Advantage Policy – Diaphragmatic/Phrenic Nerve Electrical Stimulators

Clinical Policy for Medical Necessity Review

Version: 2

Policy Number: CHP-045-2

Cohere Health UMC Approval Date: March 10, 2026

Last Annual Review: March 10, 2026

Revision: Not Applicable

Next Annual Review: March 10, 2027

Important Notices

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Policy Information:

Specialty Area: Sleep Medicine

Policy Name: Cohere Medicare Advantage Policy - Diaphragmatic/Phrenic Nerve Electrical Stimulators

Policy Number: CHP-045-2

Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Diaphragmatic/Phrenic Nerve Electrical Stimulators

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to *Cohere Medicare Advantage Policy - Diaphragmatic/Phrenic Nerve Electrical Stimulators* is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 – Related CMS Policies (NCDs or LCDs)²

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	Phrenic Nerve Stimulator	160.19	Not fully established	• Stable high cervical spinal cord injury (SCI)(C3 vertebral level or higher) • Ventilator-dependent patients with central alveolar hypoventilation syndrome • Replacement, adjustment, repair, or removal of a diaphragmatic/phrenic nerve electrical stimulation device • Non-indications for the following: ○ Amyotrophic lateral sclerosis (ALS) ○ Central sleep apnea (e.g., remedē) ○ Denervation of the diaphragm ○ Temporary respiratory insufficiency or difficult-to-wean patients on mechanical ventilation
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use NCD 160.19 and Cohere Medicare Advantage internal coverage criteria

Description

Diaphragmatic/phrenic nerve stimulators are implantable devices designed to support respiration by delivering targeted electrical stimulation to the phrenic nerve, which controls diaphragmatic contraction. By detecting cessation of breathing, these devices trigger diaphragm contraction to simulate natural respiration and have been used for short-term daily respite from mechanical ventilation in patients with high-level (C3 and higher) spinal cord injuries (SCI) as well as conditions affecting respiration, such as central alveolar hypoventilation syndrome.^{3,4} Clinical studies are ongoing related to the proposed use in central sleep apnea (CSA), amyotrophic lateral sclerosis (ALS), and difficult-to-wean mechanically ventilated individuals.⁵⁻⁸

Medical Necessity Criteria

Indications

Diaphragmatic/phrenic nerve electrical stimulation is considered appropriate if **ALL** of the following are **TRUE**:

- Age 18 years or older⁹; **AND**
- Sufficient diaphragmatic function to accommodate electrical stimulation⁹; **AND**
- Intact phrenic nerve function⁹; **AND**
- Normal chest anatomy is present for adequate implantation; **AND**
- Patient or caregiver is able to safely use the device; **AND**
- **ANY** of the following:
 - **ALL** of the following:
 - Ventilator-dependent, stable high cervical spinal cord injury (SCI)(C3 vertebral level or higher)^{3,9-12}; **AND**
 - Unable to breathe independently for at least 4 continuous hours per day without the assistance of a mechanical ventilator⁹; **OR**
 - Ventilator-dependent patients with central alveolar hypoventilation syndrome.^{4,13}

Removal, replacement, or repair/adjustment of diaphragmatic/phrenic nerve electrical stimulation is considered appropriate if **ANY** of the following is **TRUE**:

- Removal when device is no longer medically necessary; **OR**

- Replacement or repair/adjustment when there is documentation of continued medical necessity.

Non-Indications

Diaphragmatic/phrenic nerve electrical stimulation is not considered appropriate if **ANY** of the following is **TRUE**:

- Amyotrophic lateral sclerosis (ALS)^{6,14}; **OR**
- Central sleep apnea (e.g., remedē)^{5,15-17}; **OR**
- Denervation of the diaphragm; **OR**
- Temporary respiratory insufficiency or difficult-to-wean patients on mechanical ventilation^{7,18}; **OR**
- Device is not used in accordance with FDA guidelines.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
33277	Insertion of phrenic nerve stimulator transvenous sensing lead (List separately in addition to code for primary procedure)
33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)
33279	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only
33280	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)
33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator
33288	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)
93150	Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and

	programming
93151	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
93153	Interrogation without programming of implanted phrenic nerve stimulator system

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.¹

The potential clinical harms of using these criteria for diaphragmatic/phrenic nerve electrical stimulators may include:

- Adverse effects from delayed or denied treatment, such as increased risk of ventilator-induced diaphragmatic dysfunction, which may contribute to greater risk of in-hospital mortality, hospital-acquired pneumonia, oxidative stress, reduced oxygen delivery to lung tissue, and ventilator dependence.¹⁹
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for diaphragmatic/phrenic nerve electrical stimulators may include:

- Improved patient selection for diaphragmatic/phrenic nerve electrical stimulators, resulting in better long-term outcomes. Ideal candidates should be ventilator-dependent with stable high cervical spinal cord injury (SCI) (C3 vertebral level or higher) and be unable to breathe independently for at least 4 continuous hours per day without the assistance of a mechanical ventilator. According to Onders et al. (2022), tidal volume with diaphragmatic/phrenic nerve stimulation significantly exceeded the basal metabolic requirements in patients with cervical SCI.¹²
- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients with amyotrophic lateral sclerosis (ALS) who undergo diaphragmatic/phrenic nerve electrical stimulator implantation are at increased risk of not achieving effective ventilation, rapid progression to ventilatory failure, and decreased survival.⁶

- Enhanced overall patient satisfaction and healthcare experience.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Sagalow et al. (2022) conducted a systematic review examining transvenous phrenic nerve stimulation of central sleep apnea (CSA). Thirteen articles, including 232 unique patients, were evaluated; however, most articles evaluated the same patient population. While the device was found overall beneficial to patients, there were multiple limitations, including that it is only active at night when patients are lying supine. CSA is present both at nighttime and in the daytime in heart failure patients in the form of Cheyne-Stokes respirations. This is indicative of a more serious prognosis. Additionally, patients with significant heart failure are unable to lie in a supine position due to orthopnea. A meta-analysis could not be completed due to inconsistent outcome measures across the articles. The authors recommend that future studies focus on long-term outcomes and complications, independent of the initial clinical trial results.⁵

The RESCUE II multicenter, open-label, randomized controlled trial compared temporary transvenous diaphragm neurostimulation (TTDN) versus standard care in patients 18 years of age or older on mechanical ventilation for greater than or equal to 4 days, having failed at least 2 weaning attempts. One hundred twelve patients were randomized 1:1 to TTDN or standard care. It was concluded that TTDN, when combined with standard management, did not increase the proportion of successful weaning from mechanical ventilation compared with standard treatment alone. Further studies evaluating TTDN in difficult-to-wean patient populations were recommended.⁷

Ataya and colleagues (2020) conducted the RESCUE I, multicenter, open-label, prospective single-treatment-group feasibility study evaluating TTDN. Fourteen adult mechanical ventilation-dependent patients who had failed at least two weaning trials and received TTDN in conjunction with standard care were enrolled. Patients were aged 18 years or older, medically stable, and mechanically ventilated for at least 7 days. Hypovolemia, neuromuscular disorder, known or suspected phrenic nerve paralysis, terminal illness, or body mass index greater than or equal to 40 were among the study exclusion criteria. The study included 14 patients: 11 remained throughout the study, and 7 received TTDN treatment. Two patients were

unable to have the device placed because the guidewire could not be threaded through anatomical barriers. While the authors concluded that TTDN was feasible in patients who are difficult-to-wean from mechanical ventilation, the sample size was very small, and the study lacked long-term follow-up.¹⁸

Guimarães-Costa et al. (2019) evaluated diaphragm reinnervation in an ancillary analysis of the RespiStimALS (Early Diaphragm Pacing in Patients with Amyotrophic Lateral Sclerosis) randomized controlled trial (RCT). Intradiaphragmatic electromyographic recordings were collected over 31 months from 19 patients with amyotrophic lateral sclerosis (ALS) who received either active electrical stimulation (n=9) or sham stimulation (n=10). Through this mechanistic evaluation, the authors concluded that electrical stimulation delays reinnervation of denervated muscle fibers in the diaphragm, with resulting harmful effects.¹⁴

Romero et al. (2012) conducted a retrospective cohort study comparing phrenic nerve pacing (PNP) with mechanical ventilation (MV) in patients with high cervical (C1-C2) spinal cord injury (SCI) receiving permanent respiratory support. Of the 126 study participants, 38 underwent implantation of a phrenic nerve stimulator, and 88 received MV. Health-related quality of life (HRQL), long-term tolerability, and length of survival were evaluated. Although the association between PNP and length of survival was statistically significant (odds ratio: 0.98; 95% confidence interval (CI): 0.97-0.99; $P=0.04$), the effect size was very small, indicating no clinically meaningful difference between the groups. Only 44 patients (65.7%) completed the Short-Form-36 HRQL questionnaire. Overall, HRQL did not differ significantly between treatment groups, but PNP patients reported significantly greater improvement in social functioning.¹¹

In 2025, the American Academy of Sleep Medicine (AASM) published an updated clinical practice guideline on the treatment of central sleep apnea in adults. In patients with primary CSA and CSA due to heart failure, the AASM suggests using transvenous phrenic nerve stimulation (TPNS) over no transvenous phrenic nerve stimulation; however, the evidence base for this conditional recommendation was small (1 RCT, 4 observational studies) and the Grading of Recommendations Assessment, Development and Evaluation

(GRADE) certainty of evidence was determined to be very low. The AASM also noted that it may be more appropriate to consider other treatments first, as TPNS is an invasive procedure with high costs, and there is limited availability of trained electrophysiologists capable of implanting these devices.¹⁵

References

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Policy Revision History/Information

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Review History		
Version 2	03/10/2026	Annual review. Updated template, including addition of “Table 1 – Related CMS Policies” that describes Cohere definition of which LCDs/NCDs are not fully established. Cohere MA criteria updated for internal alignment across policies. Added non-indication – “Device is not used in accordance with FDA guidelines.” Rearranged bullets for improved usability and organization. Updated AASM reference. Added 2 references.



Cohere Medical Policy – Diaphragmatic/Phrenic Nerve Electrical Stimulators

Clinical Guidelines for Medical Necessity Review

Version: 1
Revision Date: March 13, 2025

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Guideline Information:

Specialty Area: Sleep Medicine

Guideline Name: Cohere Medical Policy - Diaphragmatic/Phrenic Nerve Electrical Stimulators

Date of last literature review: 03/12/2025

Document last updated: 03/12/2025

Type: ☒ Adult (18+ yo) | ☐ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Diaphragmatic/Phrenic Nerve Electrical Stimulators

Recommended Clinical Approach

The phrenic nerve controls the movement of the diaphragm to facilitate respiration by allowing air to move into the lungs. Electrical stimulation of the phrenic nerve may be achieved by the implantation of a device that can detect cessation of breathing and trigger contraction of the diaphragm to simulate natural respiration. These devices have been used for short-term daily respite from mechanical ventilation in patients with high-level (C3 and higher) spinal cord injuries (SCI) as well as conditions affecting respiration such as central alveolar hypoventilation syndrome.¹⁻² Clinical studies are ongoing related to proposed use in central sleep apnea (CSA), amyotrophic lateral sclerosis (ALS), and difficult-to-wean mechanically ventilated individuals.³⁻⁶

Medical Necessity Criteria

Indications

→ **Diaphragmatic/phrenic nerve electrical stimulation** is considered appropriate if **ALL** of the following are **TRUE**:

- ◆ The patient is 18 years of age or older⁷; **AND**
- ◆ There is sufficient diaphragmatic function to accommodate electrical stimulation⁷; **AND**
- ◆ There is intact phrenic nerve function⁷; **AND**
- ◆ Normal chest anatomy is present for adequate implantation; **AND**
- ◆ The patient and/or caregiver is able to safely use the device; **AND**
- ◆ **ANY** of the following:
 - **ALL** of the following:
 - Noninvasive or invasive ventilator-dependent, stable high cervical spinal cord injury (SCI)(C3 vertebral level or higher)^{1,7-9}; **AND**
 - The patient is unable to breathe independently for at least 4 continuous hours per day without the assistance of a mechanical ventilator^{1,7}; **OR**
 - Noninvasive or invasive ventilator-dependent patients with central alveolar hypoventilation syndrome^{2,10}; **OR**

- Replacement, adjustment, repair, or removal of a diaphragmatic/phrenic nerve electrical stimulation device when medically necessary.

NOTE: The diaphragmatic/phrenic nerve electrical stimulation device will be used according to FDA-approved indications.⁷

Non-Indications

→ **Diaphragmatic/phrenic nerve electrical stimulation** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Central sleep apnea (e.g., remedē)^{3,11-13}; **OR**
- ◆ Amyotrophic lateral sclerosis (ALS)^{4,14}; **OR**
- ◆ Temporary respiratory insufficiency or difficult-to-wean patients on mechanical ventilation^{5,15}; **OR**
- ◆ Denervation of the diaphragm.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
33277	Insertion of phrenic nerve stimulator transvenous sensing lead (List separately in addition to code for primary procedure)
33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)
33279	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only

33280	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)
33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator
33288	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)
93150	Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming
93151	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
93153	Interrogation without programming of implanted phrenic nerve stimulator system

Medical Evidence

Romero et al. (2012) completed a retrospective cohort study of cervical spinal cord injury (SCI) patients on permanent respiratory support. Potential for improved health-related quality of life (HRQL), long-term tolerability, and improved patient survival were indicators of effectiveness of the device. Of the 126 study participants, 38 patients received phrenic nerve stimulation (pacing) and 88 were mechanically ventilated. Patients included were those with high cervical SCI requiring volumetric mechanical ventilatory support from the moment of injury and exclusion criteria included active pulmonary infections, cancer, or other terminal illness. Mental disability and lack of family or caregiver support were not considered exclusions from the study. It was concluded that phrenic nerve stimulation, particularly in those younger members of the implant group, can impact long-term survival in patients with ventilator-dependent high SCI, with improved HRQL.⁹

Ataya and colleagues (2020) conducted the US-based RESCUE 1, multicenter, prospective open-label single treatment group feasibility study of adult patients for phrenic nerve stimulator implantation. These were mechanical ventilation-dependent patients who had failed at least two weaning trials and who received temporary transvenous diaphragmatic neurostimulation (TTDN) in conjunction with the standard of care. Patients in this study were adults 18 years of age or older and medically stable, having been on mechanical ventilation for at least 7 days. Hypovolemia, neuromuscular disorder, known or suspected phrenic nerve paralysis, terminal illness, or body mass index greater than or equal to 40 were among the study exclusion criteria. The study number was small with 14 patients, 11 who remained throughout the study and 7 who received the TTDN treatment. Two patients were unable to have the device placed due to inability to thread the guidewire due to potential anatomical barriers. The overall conclusion was that TTDN is safe and feasible in patients who are difficult to wean from mechanical ventilation. Future studies with greater numbers of participants are recommended.¹⁵

The RESCUE II study results were presented by Dres et al. (2021) in the American Journal of Respiratory Critical Care Medicine (American Thoracic

Society). The randomized, controlled, multi-center, open-label study focused upon patients 18 years of age or older on mechanical ventilation for greater than or equal to 4 days, having failed at least 2 weaning attempts. There were 127 eligible participants, with 112 randomized to 57 in the treatment group with temporary transvenous diaphragm neurostimulation (TTDN) and 55 in the control group. It was concluded that TTDN combined with standard management did not increase the proportion of successful weaning from mechanical ventilation when compared to solely standard treatment. Further studies were recommended.⁵

The American Academy of Sleep Medicine (AASM) maintains a 2012 guideline (Aurora et al.) for treatment of central sleep apnea with practice parameters. The literature review and meta-analyses do not reference diaphragmatic/phrenic nerve stimulation for central sleep apnea treatment and no recommendations located on this society's website currently support the use of the device.¹³

Sagalow et al. (2022) conducted a systematic review published in the American Journal of Cardiology regarding transvenous phrenic nerve stimulation of central sleep apnea. There were 232 patients in the studies examined who were implanted with the device. While the device was found overall to be of benefit to patients, there were multiple limitations, including that the device is only active at night when patients are lying supine. CSA is present both at nighttime and in the daytime in heart failure patients in the form of Cheyne–Stokes respirations. This is indicative of a more serious prognosis. Patients with significant heart failure are unable to lie in a supine position due to orthopnea. A meta-analysis was unable to be completed due to a lack of consistent outcome measures in the articles. The authors recommend additional studies in the future focusing on long-term outcomes and complications which would be independent from the initial clinical trial results.³

A 2019 publication in The American Journal of Respiratory and Critical Care Medicine (Guimarães-Costa et al.) reviews findings of two clinical trials: DiPALS (Diaphragm Pacing in Patients with Amyotrophic Lateral Sclerosis) and RespiStimALS (Early Diaphragm Pacing in Patients with Amyotrophic Lateral Sclerosis). A diaphragm biopsy substudy of the RespiStimALS protocol was

conducted on 39 patients, with 19 of these patients having left diaphragm electrical activity recording. Two of the 19 patients were eventually excluded with a resulting 17 patients (active stimulation in 8 patients and sham in 9) with electrophysiological recordings for analysis. Through this mechanistic evaluation, it was concluded that electrical stimulation delays reinnervation of denervated muscle fibers in the diaphragm with resulting harmful effect.¹⁴

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Clinical Guideline Revision History/Information

Original Date: March 13, 2025		
Review History		



Cohere Medicare Advantage Policy – Hypoglossal Nerve Stimulation Implantable Devices

Clinical Policy for Medical Necessity Review

Version: 2

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Important Notices

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Policy Information:

Specialty Area: Otolaryngology

Policy Name: Cohere Medicare Advantage Policy - Hypoglossal Nerve Stimulation Implantable Devices

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Hypoglossal Nerve Stimulation Implantable Devices

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁸

- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea \(L38276\)](#)
 - [Billing and Coding: Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea \(A58075\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38307\)](#)
 - [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57149\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38398\)](#)
 - [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A56953\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38387\)](#)
 - [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57092\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38310\)](#)
 - [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57948\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38312\)](#)
 - [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57949\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38385\)](#)

- [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A56938\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38528\)](#)
- [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57944\)](#)

Description

Hypoglossal nerve stimulation (HGNS) is a safe and effective second-line treatment for patients with moderate to severe obstructive sleep apnea (OSA) who have difficulty tolerating continuous positive airway pressure (CPAP).⁹ The implantation of the HGNS is a surgical procedure, typically performed in an outpatient setting, that requires a patient to undergo a preoperative evaluation by a sleep specialist or otolaryngologist.^{10,11}

Medical Necessity Criteria

Indications

A hypoglossal nerve stimulation (HGNS) implantable device is considered appropriate if **ALL** of the following are **TRUE**¹⁻⁸:

- Patient is 22 years or older; **AND**
- Body mass index (BMI) less than 35 kg/m²; **AND**
- Confirmed absence of complete concentric collapse at the soft palate level by a drug-induced sleep endoscopy (DISE) procedure; **AND**
- A polysomnography (PSG) or home sleep apnea study demonstrating less than 25% central events is performed within 24 months of first consultation for HGNS implant^{12,13}; **AND**
- Use of HNS devices with United States (U.S.) Food and Drug Administration (FDA)-approval for implantation to treat OSA (e.g., Inspire® II Upper Airway Stimulator); **AND**
- The patient has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **AND**
- Apnea-hypopnea index (AHI) is 15 to 65 events per hour; **AND**
- Shared decision-making (SDM) between the beneficiary, sleep physician, and qualified otolaryngologist (if they are not the same) who determines that the beneficiary demonstrates continuous positive airway pressure

(CPAP) failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as CPAP machine-derived compliance reporting with usage less than 4 hours a night for at least 70% of the nights in 1 month, or the CPAP has been returned) despite CPAP interface and/or setting optimizations.

Non-Indications

A hypoglossal nerve stimulation implantable device is not considered appropriate if **ANY** of the following is **TRUE**¹⁻⁸:

- The patient has **ANY** of the following:
 - Anatomical findings that would compromise performance of the device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale); **OR**
 - Central and mixed apneas that make up more than 25% of total AHI; **OR**
 - Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months); **OR**
 - An implantable device that could produce unintended interaction with the HGNS implant system; **OR**
 - Neuromuscular disease; **OR**
 - Hypoglossal nerve palsy; **OR**
 - Severe restrictive or obstructive pulmonary disease; **OR**
 - Moderate-to-severe pulmonary arterial hypertension; **OR**
 - Severe valvular heart disease; **OR**
 - New York Heart Association class III or IV heart failure; **OR**
 - Condition or procedure that has compromised neurological control of the upper airway; **OR**
 - Persistent uncontrolled hypertension despite medication use; **OR**
 - Active, serious mental illness that reduces the ability to carry out activities of daily living (ADLs) and would interfere with the patient's ability to operate the HGNS implantable device and/or report problems to an attending provider; **OR**
- The patient is, or plans to become, pregnant; **OR**
- The patient requires magnetic resonance imaging (MRI) with model 3024; **OR**
- The patient is unable or does not have the necessary assistance to operate the sleep remote; **OR**
- The patient has had a recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months); **OR**

- The request is for a nerve stimulator not specifically defined for the hypoglossal nerve (e.g., CPT 64568).

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64582	Insertion of hypoglossal nerve stimulator electrode and generator and breathing sensor electrode
64583	Revision or replacement of hypoglossal nerve stimulator electrode and breathing sensor electrode with connection to existing generator
64584	Removal of hypoglossal nerve neurostimulator electrode and generator and breathing sensor electrode array

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria may include:

- Adverse outcomes associated with the implantation include pneumothorax, pleural effusion, and the device lead drifting into the pleural space.^{[14](#)}
- Discomfort from or intolerance to the HGNS stimulation.^{[15](#)}
- An HGNS device may malfunction and/or fail, and while it can be replaced, reimplanted, or removed, these procedures are accompanied by the inherent risks of surgical revisions.^{[14](#)}
- Wollny et al. (2024) conducted a systematic review of adverse events and complications that resulted from HGNS implantation and found the procedure to have a positive patient safety profile while also identifying a variety of adverse events and side effects, including tongue abrasion, post-operative pain, neuropraxia, and hematoma.^{[16](#)}
- Increased healthcare costs and complications may result from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Marked and enduring improvements in patients' sleep-related quality of life.^{[17,18](#)}
- Consistent reductions in insomnia, sleepiness, and depressive symptoms.^{[17,18](#)}

- A safe and effective treatment for moderate-to-severe obstructive sleep apnea (OSA) for adults unable to tolerate continuous positive airway pressure (CPAP) treatment.[19,20](#)
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Evidence

A cohort study of 85 patients receiving HGNS sought to determine and compare the improvements associated with HGNS to patient-related outcomes attributed to positive airway pressure therapy. The study found consistent and enduring improvements regarding insomnia, sleepiness, quality of life, and depressive symptoms. These improvements were comparable to improvements associated with PAP therapy.¹⁸

Bellamkonda et al. (2021) conducted an FDA database analysis of adverse events in hypoglossal nerve stimulator implantation, which identified common technical difficulties and complications associated with the procedure. The analysis included 134 adverse events across 132 patients and a 5-year inclusion period. Common complications included device migration and infection.¹⁴

A systematic review and meta-analysis conducted by Constantino et al. (2019) found HGNS to be a safe and effective surgical treatment for adults with moderate-to-severe OSA who have trouble adhering to continuous positive airway pressure (CPAP) treatment. The review and meta-analysis included 12 studies with a combined 350 patients, of which 6% reported having serious adverse events related to the HGNS implant after their 1- and 5-year follow-ups. The authors conclude that HGNS represents a promising alternative to CPAP, as long-term adherence to CPAP treatment is low and devices are frequently misused.¹⁹

A pooled cohort analysis of four observational cohorts that included 584 patients found hypoglossal nerve stimulation (HGNS) to be associated with marked improvements in patients' sleep-related quality of life. The study, conducted by Kent et al. (2019), examined the association of HGNS with obstructive sleep apnea (OSA) severity, daytime sleepiness, and sleep-related quality of life. Patients implanted with an HGNS device experienced significant reductions in their apnea-hypopnea index (AHI) burden at six and twelve months and saw substantial improvements in their subjective daytime sleepiness.¹⁷

A 2015 systematic review and meta-analysis that included six prospective studies with 200 patients found hypoglossal nerve stimulation therapy to be a safe and cost-effective procedure for patients with moderate to severe OSA who were unable to tolerate or adhere to CPAP therapy. The meta-analysis included studies with quantitative pre- and post-implantation outcomes, including the apnea-hypopnea index, the oxygen desaturation index, and the Epworth sleepiness scale, of the HGNS devices. The review analyzed three types of HGNS devices (the HGNS system, the Aura600 system, and the Inspire II Upper Airway Stimulation device) and found consistent improvements in OSA outcomes across device types, all reporting stable patient outcome results 12 months after implantation.^{[20](#)}

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Policy Revision History/Information

Original Date: March 13, 2025		
Review History		
Version 1.1	03/18/2025	Updated policy per CMS revisions for 03/06/25. Updated Links and Bookmarks.
Version 2	07/31/2025	Updated links to superseded Billing and Coding articles A57948 and A57949 (corresponding to LCDs L38310 and L38312). Added CPT code 64568. Added non-indication, "The request is for a nerve stimulator not specifically defined for the hypoglossal nerve (e.g., CPT 64568)." Revised minimum age from 18 to 22 in alignment with LCDs. Removed non-indication "BMI greater than 35 kg/m²" to omit redundancy of an existing indication.



Cohere Medicare Advantage Policy – Hypoglossal Nerve Stimulation (HGNS) Implantable Device

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: March 13, 2025

Important Notices

Notices & Disclaimers:

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Guideline Information:

Specialty Area: Otolaryngology

Guideline Name: Hypoglossal Nerve Stimulation (HGNS) Implantable Device

Date of last literature review: 02/28/2025

Document last updated: 3/12/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Hypoglossal Nerve Stimulation Implantable Device

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁸

- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea \(L38276\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(38307\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(38398\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(38387\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(38310\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(38312\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(38385\)](#)
- [Local Coverage Determination \(LCD\). Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(38528\)](#)
- [Billing and Coding: Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea \(A58075\)](#)
- [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57149\)](#)
- [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A56953\)](#)

- [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(57092\)](#)
- [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57948\)](#)
- [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57949\)](#)
- [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A56938\)](#)
- [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57944\)](#)
- [Billing and Coding: Category III Codes \(A56902\)](#)
- [Billing and Coding: Polysomnography and Other Sleep Studies \(A56903\)](#)

Recommended Clinical Approach

Hypoglossal nerve stimulation (HGNS) is a safe and effective second-line treatment for patients with moderate to severe obstructive sleep apnea (OSA) who have difficulty tolerating continuous positive airway pressure (CPAP).⁹ The implantation of the HGNS is a surgical procedure, typically performed in an outpatient setting, and requires a patient to undergo a preoperative evaluation by a sleep specialist or otolaryngologist. Before the HGNS implantation, a drug-induced endoscopy should be performed to confirm the absence of a complete concentric collapse of the soft palate, as a complete concentric collapse of the retropalatal airway is a contraindication for HGNS.¹⁰ To be eligible for HGNS, patients must have been diagnosed with moderate to severe OSA using the apnea-hypopnea index standards and have been unable to tolerate or adhere to CPAP therapy.¹¹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of hypoglossal nerve stimulation (HGNS) implantable devices. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:¹²⁻¹⁴

- Adverse outcomes associated with the implantation include pneumothorax, pleural effusion, and the device lead drifting into the pleural space.¹²
- Discomfort from or intolerance to the HGNS stimulation.¹³
- An HGNS device may malfunction and/or fail, and while it can be replaced, reimplanted, or removed, these procedures are accompanied by the inherent risks of surgical revisions.¹²
- Wollny et al. (2024) conducted a systematic review of adverse events and complications that resulted from HGNS implantation and found the procedure to have a positive patient safety profile while also identifying a variety of adverse events and side effects, including tongue abrasion, post-operative pain, neuropraxia, and hematoma.¹⁴
- Increased healthcare costs and complications may result from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:¹⁴⁻¹⁸

- Marked and enduring improvements in patients' sleep-related quality of life.^{15,16}
- Consistent reductions in insomnia, sleepiness, and depressive symptoms.^{14,16}
- A safe and effective treatment for moderate-to-severe obstructive sleep apnea (OSA) for adults unable to tolerate continuous positive airway pressure (CPAP) treatment.^{17,18}
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- **A hypoglossal nerve stimulation (HGNS) implantable device** is considered appropriate if **ALL** of the following are **TRUE**¹⁻⁸:
- ◆ Patient is 18 years or older; **AND**
 - ◆ Body mass index (BMI) less than 35 kg/m²; **AND**
 - ◆ Confirmed absence of complete concentric collapse at the soft palate level by a drug-induced sleep endoscopy (DISE) procedure; **AND**
 - ◆ A polysomnography (PSG) or home sleep apnea study demonstrating less than 25% central events is performed within 24 months of first consultation for HGNS implant^{19,20}; **AND**
 - ◆ Use of HNS devices with United States (U.S.) Food and Drug Administration (FDA)-approval for implantation to treat OSA (e.g., Inspire® II Upper Airway Stimulator); **AND**
 - ◆ The patient has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **AND**
 - ◆ Apnea-hypopnea index (AHI) is 15 to 65 events per hour; **AND**
 - ◆ Shared decision-making (SDM) between the beneficiary, sleep physician, and qualified otolaryngologist (if they are not the same) who determines that the beneficiary demonstrates continuous positive airway pressure (CPAP) failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as CPAP machine-derived compliance reporting with usage less than 4 hours a night for at least 70% of the nights in 1 month, or the CPAP has been returned) despite CPAP interface and/or setting optimizations.

Non-Indications

- **A hypoglossal nerve stimulation implantable device** is not considered appropriate if **ANY** of the following is **TRUE**¹⁻⁸:
- ◆ The patient has **ANY** of the following:

- Anatomical findings that would compromise performance of the device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale); **OR**
- Body mass index (BMI) greater than 35 kg/m²; **OR**
- Central and mixed apneas that make up more than 25% of total AHI; **OR**
- Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months); **OR**
- An implantable device that could produce unintended interaction with the HGNS implant system; **OR**
- Neuromuscular disease; **OR**
- Hypoglossal nerve palsy; **OR**
- Severe restrictive or obstructive pulmonary disease; **OR**
- Moderate-to-severe pulmonary arterial hypertension; **OR**
- Severe valvular heart disease; **OR**
- New York Heart Association class III or IV heart failure; **OR**
- Condition or procedure that has compromised neurological control of the upper airway; **OR**
- Persistent uncontrolled hypertension despite medication use; **OR**
- Active, serious mental illness that reduces the ability to carry out activities of daily living (ADLs) and would interfere with the patient's ability to operate the HGNS implantable device and/or report problems to an attending provider; **OR**
- ◆ The patient is, or plans to become, pregnant; **OR**
- ◆ The patient requires magnetic resonance imaging (MRI) with model 3024; **OR**
- ◆ The patient is unable or does not have the necessary assistance to operate the sleep remote; **OR**
- ◆ The patient has had a recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months).

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64582	Insertion of hypoglossal nerve stimulator electrode and generator and breathing sensor electrode
64583	Revision or replacement of hypoglossal nerve stimulator electrode and breathing sensor electrode with connection to existing generator
64584	Removal of hypoglossal nerve neurostimulator electrode and generator and breathing sensor electrode array

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

A cohort study of 85 patients receiving HGNS sought to determine and compare the improvements associated with HGNS to patient-related outcomes attributed to positive airway pressure therapy. The study found consistent and enduring improvements regarding insomnia, sleepiness, quality of life, and depressive symptoms. These improvements were comparable to improvements associated with PAP therapy.¹⁶

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Review History		



Cohere Medical Policy – Hypoglossal Nerve Stimulation Implantable Devices

Clinical Policy for Medical Necessity Review

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Policy Information:

Specialty Area: Otolaryngology

Policy Name: Cohere Medical Policy - Hypoglossal Nerve Stimulation Implantable Devices

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Hypoglossal Nerve Stimulation Implantable Devices

Cohere Health takes an evidence-based approach to reviewing sleep medicine diagnostic testing, durable medical equipment (DME), and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior sleep testing, and details of previous treatments. Sleep medicine diagnostic testing, DME, and procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as duplicate or repeat sleep testing—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- Repeat sleep testing due to technical issues—such as signal artifact or loss of signal—may not be considered medically necessary, as it is the responsibility of the sleep testing center to deliver appropriate, high-quality studies as originally authorized. Similarly, repeat sleep testing requested at a different facility based solely on provider preference may not be approved for medical necessity.
- When there are multiple sleep tests requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.

- Why prior sleep tests were inconclusive or why additional/follow-up studies are needed.
- How the results will impact patient management or treatment decisions.

Description

Hypoglossal nerve stimulation (HGNS) is a safe and effective second-line treatment for patients with moderate to severe obstructive sleep apnea (OSA) who have difficulty tolerating continuous positive airway pressure (CPAP).¹ The implantation of the HGNS is a surgical procedure, typically performed in an outpatient setting, that requires a patient to undergo a preoperative evaluation by a sleep specialist or otolaryngologist.²⁻⁴

Medical Necessity Criteria

Indications

A hypoglossal nerve stimulation (HGNS) implantable device is considered appropriate if **ALL** of the following are **TRUE**⁵⁻¹⁰:

- Clinically documented failure of, or intolerance to, continuous positive airway pressure (CPAP) therapy; **AND**
- The absence of **ANY** of the following anatomical findings that may inhibit the upper airway stimulation⁵:
 - Complete concentric collapse at the soft palate level by a drug-induced sleep endoscopy (DISE)^{6,7}; **OR**
 - For patients under the age of 22, tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale^{6,11,12}; **AND**
- **ANY** of the following^{8,11,12}:
 - The patient is 18 years of age or older and has **ALL** of the following:
 - Body mass index (BMI) less than 40 kg/m²; **AND**
 - AHI shows 15 to 100 events per hour with less than 25% central and mixed apneas⁹; **OR**
 - The patient is 10-18 years of age with Down syndrome and has **ALL** of the following¹⁰:
 - BMI less than or equal to the 95th percentile for the patient's age and gender; **AND**
 - A polysomnography (PSG) or home sleep apnea study demonstrating <25% central events; **AND**
 - Absence of tracheostomy use during sleep; **AND**

- Absence of a complete blockage or concentric collapse of the soft palate level confirmed by drug induced sleep endoscopy; **AND**
- Contraindication for or not effectively treated with a prior adenotonsillectomy; **AND**
- The device is used in accordance with FDA guidelines.^{11,12}

Non-Indications

A hypoglossal nerve stimulation (HGNS) implantable device is not considered appropriate if **ANY** of the following is **TRUE**^{5,6,10}:

- The patient has **ANY** of the following:
 - Central apneas that make up more than 25% of total AHI^{10,13}; **OR**
 - Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months); **OR**
 - An implantable device that could produce unintended interaction with the HGNS implant system; **OR**
 - Neuromuscular disease; **OR**
 - Hypoglossal-nerve palsy; **OR**
 - Severe restrictive or obstructive pulmonary disease; **OR**
 - Moderate-to-severe pulmonary arterial hypertension; **OR**
 - Severe valvular heart disease; **OR**
 - New York Heart Association class III or IV heart failure; **OR**
 - Condition or procedure that has compromised neurological control of the upper airway; **OR**
 - Persistent uncontrolled hypertension despite medication use; **OR**
 - Active, serious mental illness that reduces the ability to carry out activities of daily living (ADLs) and would interfere with the patient's ability to operate the HGNS implantable device and/or report problems to an attending provider; **OR**
- The patient is, or plans to become, pregnant¹⁰; **OR**
- The patient requires magnetic resonance imaging (MRI) with model 3024; **OR**
- The patient is unable or does not have the necessary assistance to operate the sleep remote; **OR**
- The request is for a nerve stimulator not specifically defined for the hypoglossal nerve (e.g., CPT 64568).

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64582	Insertion of hypoglossal nerve stimulator electrode and generator and breathing sensor electrode
64583	Revision or replacement of hypoglossal nerve stimulator electrode and breathing sensor electrode with connection to existing generator
64584	Removal of hypoglossal nerve neurostimulator electrode and generator and breathing sensor electrode array

Medical Evidence

Bellamkonda et al. (2021) conducted a Food and Drug Administration database analysis of adverse events in hypoglossal nerve stimulator implantation, identifying common technical difficulties and complications associated with the procedure. The analysis included 134 adverse events across 132 patients and a 5-year inclusion period. Common complications included device migration and infection.¹⁴

A pooled cohort analysis of four observational cohorts that included 584 patients found hypoglossal nerve stimulation (HGNS) to be associated with marked improvements in patients' sleep-related quality of life. The study examined the association of HGNS with obstructive sleep apnea (OSA) severity, daytime sleepiness, and sleep-related quality of life. Patients implanted with an HGNS device experienced significant reductions in their apnea-hypopnea index (AHI) burden at six and twelve months and saw substantial improvements in their subjective daytime sleepiness.¹

A systematic review and meta-analysis conducted by Constantino et al. (2020) found HGNS to be a safe and effective surgical treatment for adults with moderate-to-severe OSA who have trouble adhering to continuous positive airway pressure (CPAP) treatment. The review and meta-analysis included 12 studies with a combined 350 patients, of which 6% reported having serious adverse events related to the HGNS implant after their 1- and 5-year follow-ups. The authors conclude that HGNS represents a promising alternative to CPAP, as long-term adherence to CPAP treatment is low and devices are frequently misused.¹⁵

A 2015 systematic review and meta-analysis that included six prospective studies with 200 patients found hypoglossal nerve stimulation therapy to be a safe and cost-effective procedure for patients with moderate to severe OSA who were unable to tolerate or adhere to CPAP therapy. The meta-analysis included studies with quantitative pre- and post-implantation outcomes, including the apnea-hypopnea index, the oxygen desaturation index, and the Epworth sleepiness scale, of the HGNS devices. The review analyzed three types of HGNS devices (the HGNS system, the Aura600 system, and the Inspire II Upper Airway Stimulation device) and found consistent improvements in

OSA outcomes across device types, all reporting stable patient outcome results 12 months after implantation.¹⁶

A cohort study of 85 patients receiving HGNS sought to determine and compare the improvements associated with HGNS to patient-related outcomes attributed to positive airway pressure therapy. The study found consistent and enduring improvements regarding insomnia, sleepiness, quality of life, and depressive symptoms. These improvements were comparable to improvements associated with PAP therapy.¹⁷

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Policy Revision History/Information

Original Date: March 13, 2025		
Review History		
Version 2	07/31/2025	Added CPT code 64568. Added non-indication, "The request is for a nerve stimulator not specifically defined for the hypoglossal nerve (e.g., CPT 64568)." Removed extraneous information and references from the "Description" section. Updated indications in alignment with the FDA Premarket Approval and Summary of Safety and Effectiveness Data for the Inspire® Upper Airway Stimulator, including: clarifying "patients under the age of 22 [for tonsil size 3 or 4];" updating BMI from 35 to 40 kg/m²; updating patient age range from 13-18 to 10-18 for patients with Down syndrome. Added indications: "Absence of tracheostomy use during sleep;" "Absence of a complete blockage or concentric collapse of the soft palate level confirmed by drug induced sleep endoscopy;" and "Contraindication for or not effectively treated with a prior adenotonsillectomy." Added indication, "The device is used in accordance with FDA guidelines." Removed non-indications: "Anatomic findings that would compromise the performance of the device;" "BMI greater than 35 kg/m²;" and "Complete concentric collapse at the soft palate level" to omit redundancy of existing indications.



Cohere Medical Policy – Hypoglossal Nerve Stimulation (HGNS) Implantable Devices

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: March 13, 2025

Important Notices

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Guideline Information:

Specialty Area: Otolaryngology

Guideline Name: Hypoglossal Nerve Stimulation (HGNS) Implantable Devices

Date of last literature review: 3/10/2025

Document last updated: 3/12/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Hypoglossal Nerve Stimulation Implantable Devices

Recommended Clinical Approach

Hypoglossal nerve stimulation (HGNS) is a safe and effective second-line treatment for patients with moderate to severe obstructive sleep apnea (OSA) who have difficulty tolerating continuous positive airway pressure (CPAP).¹ The implantation of the HGNS is a surgical procedure, typically performed in an outpatient setting, and requires a patient to undergo a preoperative evaluation by a sleep specialist or otolaryngologist.² Before the HGNS implantation, a drug-induced endoscopy should be performed to confirm the absence of a complete concentric collapse of the soft palate, as the condition is a contraindication for HGNS.³ To be eligible for HGNS, patients must be diagnosed with moderate to severe OSA using the apnea-hypopnea index (AHI) standards, and unable to tolerate or adhere to CPAP therapy.⁴

An HGNS implantable device may migrate or become infected.⁵ Other adverse outcomes associated with the implantation, while rare, include pneumothorax, pleural effusion, and the device lead drifting into the pleural space. Some patients may also experience discomfort from or intolerance to the HGNS stimulation.⁶ Furthermore, an HGNS device may malfunction and/or fail, and while it can be replaced, reimplanted, or removed, these procedures are accompanied by the inherent risks of surgical revisions.⁷ Wollny et al (2024) conducted a systematic review of adverse events and complications that resulted from HGNS implantation. The authors concluded that the procedure has a positive patient safety profile while identifying a variety of adverse events and side effects, including tongue abrasion, post-operative pain, neuropraxia, and hematoma.⁸ Increased healthcare costs and complications may result from the inappropriate use of emergency services and additional treatments.

Medical Necessity Criteria

Indications

→ **A hypoglossal nerve stimulation (HGNS) implantable device** is considered appropriate if **ALL** of the following are **TRUE**^{6,9-13}:

- ◆ Clinically documented failure of, or intolerance to, continuous positive airway pressure (CPAP) therapy; **AND**
- ◆ The absence of **ANY** of the following anatomical findings that may inhibit the upper airway stimulation⁶:
 - Complete concentric collapse at the soft palate level by a drug-induced sleep endoscopy (DISE)^{9,10}; **OR**
 - Tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale⁹; **AND**
- ◆ **ANY** of the following¹¹:
 - The patient is 18 years of age or older and has **ALL** of the following:
 - Body mass index (BMI) less than 35 kg/m²; **AND**
 - AHI shows 15 to 65 events per hour with less than 25% central and mixed apneas¹²; **OR**
 - The patient is 13-18 years of age with Down syndrome and has **ALL** of the following¹³:
 - BMI less than or equal to the 95th percentile for individual's age and gender; **AND**
 - A polysomnography (PSG) or home sleep apnea study demonstrating <25% central events.

Non-Indications

→ **A hypoglossal nerve stimulation implantable device** is not considered appropriate if **ANY** of the following is **TRUE**^{6,13}:

- ◆ The patient has **ANY** of the following:
 - Anatomical findings that would compromise the performance of the device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale)^{6,13}; **OR**
 - Body mass index (BMI) greater than 35 kg/m²; **OR**
 - Complete concentric collapse at the soft palate level^{9,10,14}; **OR**
 - Central apneas that make up more than 25% of total AHI^{13,14}; **OR**
 - Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months); **OR**

- An implantable device that could produce unintended interaction with the HGNS implant system; **OR**
- Neuromuscular disease; **OR**
- Hypoglossal-nerve palsy; **OR**
- Severe restrictive or obstructive pulmonary disease; **OR**
- Moderate-to-severe pulmonary arterial hypertension; **OR**
- Severe valvular heart disease; **OR**
- New York Heart Association class III or IV heart failure; **OR**
- Condition or procedure that has compromised neurological control of the upper airway; **OR**
- Persistent uncontrolled hypertension despite medication use; **OR**
- Active, serious mental illness that reduces the ability to carry out activities of daily living (ADLs) and would interfere with the patient's ability to operate the HGNS implantable device and/or report problems to an attending provider; **OR**
- ◆ The patient is, or plans to become, pregnant¹³; **OR**
- ◆ The patient requires magnetic resonance imaging (MRI) with model 3024; **OR**
- ◆ The patient is unable or does not have the necessary assistance to operate the sleep remote.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64582	Insertion of hypoglossal nerve stimulator electrode and generator and breathing sensor electrode
64583	Revision or replacement of hypoglossal nerve stimulator electrode and breathing sensor electrode

	with connection to existing generator
64584	Removal of hypoglossal nerve neurostimulator electrode and generator and breathing sensor electrode array

Medical Evidence

Bellamkonda et al. (2021) conducted a Food and Drug Administration database analysis of adverse events in hypoglossal nerve stimulator implantation, identifying common technical difficulties and complications associated with the procedure. The analysis included 134 adverse events across 132 patients and a 5-year inclusion period. Common complications included device migration and infection.⁷

A pooled cohort analysis of four observational cohorts that included 584 patients found hypoglossal nerve stimulation (HGNS) to be associated with marked improvements in patients' sleep-related quality of life. The study examined the association of HGNS with obstructive sleep apnea (OSA) severity, daytime sleepiness, and sleep-related quality of life. Patients implanted with an HGNS device experienced significant reductions in their apnea-hypopnea index (AHI) burden at six and twelve months and saw substantial improvements in their subjective daytime sleepiness.¹

A systematic review and meta-analysis conducted by Constantino et al. (2020) found HGNS to be a safe and effective surgical treatment for adults with moderate-to-severe OSA who have trouble adhering to continuous positive airway pressure (CPAP) treatment. The review and meta-analysis included 12 studies with a combined 350 patients, of which 6% reported having serious adverse events related to the HGNS implant after their 1- and 5-year follow-ups. The authors conclude that HGNS represents a promising alternative to CPAP, as long-term adherence to CPAP treatment is low and devices are frequently misused.¹⁵

A 2015 systematic review and meta-analysis that included six prospective studies with 200 patients found hypoglossal nerve stimulation therapy to be a safe and cost-effective procedure for patients with moderate to severe OSA who were unable to tolerate or adhere to CPAP therapy. The meta-analysis included studies with quantitative pre- and post-implantation outcomes, including the apnea-hypopnea index, the oxygen desaturation index, and the Epworth sleepiness scale, of the HGNS devices. The review analyzed three types of HGNS devices (the HGNS system, the Aura600 system, and the Inspire II Upper Airway Stimulation device) and found consistent improvements in OSA outcomes across device types, all reporting stable patient outcome results 12 months after implantation.¹⁶

A cohort study of 85 patients receiving HGNS sought to determine and compare the improvements associated with HGNS to patient-related outcomes attributed to positive airway pressure therapy. The study found consistent and enduring improvements regarding insomnia, sleepiness, quality of life, and depressive symptoms. These improvements were comparable to improvements associated with PAP therapy.¹⁷

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Clinical Guideline Revision History/Information

Original Date: March 13, 2025		
Review History		



Cohere Medicare Advantage Policy – Obstructive Sleep Apnea Surgeries

Clinical Guidelines for Medical Necessity Review

Version: 1.1

Cohere Health UMC Approval Date: February 13, 2025

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Revision Date: August 7, 2025

Next Annual Review: Not Applicable

Important Notices

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Guideline Information:

Specialty Area: Sleep Medicine

Guideline Name: Cohere Medicare Advantage Policy - Obstructive Sleep Apnea Surgeries

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Obstructive Sleep Apnea Surgeries

Related CMS Documents

Please refer to [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻²

- [Local Coverage Determination \(LCD\): Surgical treatment of obstructive sleep apnea \(OSA\) \(L34526\)](#)
- [Billing and Coding: Surgical treatment of obstructive sleep apnea \(OSA\) \(A56905\)](#)

Recommended Clinical Approach

Obstructive sleep apnea (OSA) is a condition where multiple episodes of partial or complete closure of the upper airway during sleep may occur. These often frequent episodes may lead to pauses in breathing (apnea or hypopnea) that can last for greater than 10 seconds, and may be followed by awakening or rapid breathing. Diagnostic testing is necessary to determine the presence of OSA. While non-surgical treatments exist (e.g., positive airway pressure [PAP]), surgery may be recommended to reduce the risk of hypertension, atrial fibrillation, heart failure, and other serious associated conditions due to lack of oxygen in the bloodstream. Both adults and children may be affected by OSA.³⁻⁴

Medical Necessity Criteria

Indications

Obstructive sleep apnea (OSA) surgeries are considered appropriate if **ALL** of the following are **TRUE**^{1, 7-11}:

- **ANY** of the following procedures^{1, 8-9}:
 - Hyoid myotomy and suspension¹²⁻¹³; **OR**
 - Tongue base suspension, permanent suture technique¹; **OR**

- Palatopharyngoplasty (uvulopalatopharyngoplasty, uvulopharyngoplasty); **OR**
- Pharyngoplasty; **AND**
- Confirmed diagnosis* of OSA^{1,10,14}; **AND**
- Respiratory disturbance index or apnea-hypopnea index greater than 15 (moderate to severe OSA)^{1,15}; **AND**
- Documented counseling by a physician, with recognized training in sleep disorders about the potential benefits and risks of the surgery¹; **AND**
- **ANY** of the following:
 - Evidence of retrolingual, retropalatal, or combination retropalatal/retrolingual obstruction as the cause of the OSA¹; **OR**
 - History of prior UPPP, and **ALL** of the following are **TRUE**:
 - Failure of previous UPPP¹; **AND**
 - The request is for hyoid myotomy and suspension; **AND**
- Failure or intolerance of positive airway pressure (PAP) therapy or other appropriate non-invasive treatment. ^{1,5-6,16-17}

***NOTE:** OSA diagnosis has been confirmed by a physician specializing in sleep disorders by polysomnography in a facility-based laboratory or with a home-based study using a technically adequate device under the supervision of a physician specializing in sleep disorders.¹⁸

Non-Indications

Obstructive sleep apnea surgeries are not considered appropriate if **ANY** of the following is **TRUE**^{1,3,8}:

- PAP and/or oral appliance therapy have not been attempted; **OR**
- Non-obstructive sleep apnea has been documented.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
21685	Hyoid myotomy and suspension
41512	Tongue base suspension, permanent suture technique
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
42950	Pharyngoplasty (plastic or reconstructive operation on pharynx)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of obstructive sleep apnea surgeries. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Potential risks of OSA surgeries include short-term postoperative complications such as swallowing difficulties, velopharyngeal insufficiency, infection, or taste disturbances. Long-term adverse effects may include failure to provide a cure for the OSA as well as intolerance to PAP therapy (Smith et al. 2015).⁵
- Consideration of potential delays or denials in treatment leading to worsened patient outcomes. Inability to perform OSA surgery due to delays or denials in treatment can result in cardiovascular compromise for the patient as well as decreased quality of life due to inadequate sleep. Individuals with increased body mass index (BMI) may be at

greater risk for OSA and its complications, according to a 2021 guideline for the American Academy of Sleep Medicine by Kent et al.⁶

- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The potential clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to obstructive sleep apnea (OSA) surgeries. OSA surgical approaches may improve sleep quality for individuals who have not been successfully treated with non-surgical interventions such as positive airway pressure (PAP) therapy due to airway obstruction in the palatal and lingual regions.
- Reduction in complications and adverse effects from unnecessary procedures. It is crucial to avoid unnecessary surgery, as future additional invasive management may be required.
- Appropriate management of obstructive sleep apnea which has not been successfully treated by non-surgical interventions. Individuals may not have been able to tolerate PAP therapy due to claustrophobia or other intolerance, or their OSA symptoms may have persisted despite the use of PAP therapy.
- Enhanced overall patient satisfaction and healthcare experience. Individuals may experience better overall health following OSA surgery as their sleep improves and there is a reduction in cardiovascular complications and improved quality of life.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Evidence

The American Academy of Sleep Medicine (AASM) (Kent et al.) published a 2021 guideline for referral of adults with OSA for surgical consultation. The committee concluded with a strong recommendation that patients with OSA and a body mass index greater than 40 kg/m², when unaccepting or intolerant of PAP therapy, be referred to a sleep surgeon. A strong recommendation was given for discussion of referral to a bariatric surgeon for adults with OSA and BMI greater than or less than 35 kg/m². Conditional recommendations were given for sleep surgeon referrals for adults with OSA and BMI less than 40 kg/m² with inadequate PAP adherence due to side effects and a PAP trial as initial therapy in adults with OSA and a major upper airway anatomic abnormality prior to surgical consult.⁶

Aurora et al. (2010) developed practice parameters for surgical modifications of the upper airway for obstructive sleep apnea in adults for the American Academy of Sleep Medicine (AASM). In this systematic review, the group recommended diagnosis of sleep apnea before initiating surgery, and included procedures such as tracheostomy, maxillo-mandibular advancement (MMA), laser-assisted uvulopalatoplasty (LAUP), uvulopalatopharyngoplasty (UPPP), radiofrequency ablation (RFA), and palatal implants. UPPP as a sole procedure was stated not to reliably normalize the apnea-hypopnea index (AHI) in moderate to severe OSA syndrome. The other procedures evaluated were stated generally to be acceptable following a trial of positive airway pressure (PAP) therapy, although the group concluded that there is a lack of rigorous data evaluating outcome measures and which populations would benefit from these surgical treatments.¹¹

Ong et al. (2017) conducted a retrospective study of 19 patients who underwent hyoid myotomy and suspension (HMS) without concurrent palatal or tongue base sleep surgery. The apnea-hypopnea index (AHI) was required to be greater than 30 indicating severe sleep apnea, and the mean BMI in these patients was 30.6 (range of 22.9–43.4). The mean age of patients studied was 55.3 years (range of 31–76 years of age). Endoscopic sinus surgery and septoplasty were the most commonly performed concurrent procedures. Following the procedure, mean AHI improved in these patients

from 39.7 to 22.6. Surgical success was defined as a greater than 50% reduction in AHI and postoperative AHI less than 20 events per hour, and was achieved in 47.4% of patients (9 of 19). The effect on daytime sleepiness was unclear.¹²

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Policy Revision History/Information

Original Date: February 13, 2025		
Review History		
Version 1.1	08/07/2025	Updated links to and references for L34256 and A56905, according to the 06/25/2025 update of CMS LCD L34526



Cohere Medical Policy – Obstructive Sleep Apnea Surgeries (Non-Covered Procedures)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: February 13, 2025

Important Notices

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Guideline Information:

Specialty Area: Sleep Medicine

Guideline Name: Cohere Medical Policy – Obstructive Sleep Apnea Surgeries (Non-Covered Procedures)

Literature review current through: 02/12/2025

Document last updated: 02/12/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Obstructive Sleep Apnea Surgeries (Non-Covered Procedures)

Recommended Clinical Approach

These services are clinically unproven and not medically necessary.

Obstructive sleep apnea (OSA) is a condition where multiple episodes of partial or complete closure of the upper airway during sleep may occur. These often frequent episodes may lead to pauses in breathing (apnea or hypopnea) that can last for greater than 10 seconds, and may be followed by awakening or rapid breathing. Both adults and children may be affected by OSA. Diagnostic testing is necessary to determine the presence of OSA. While non-surgical treatments exist (e.g., positive airway pressure [PAP], oral appliance therapy), surgery may be recommended to reduce the risk of hypertension, atrial fibrillation, heart failure, and other serious associated conditions due to lack of oxygen in the bloodstream. While there are several established and clinically proven OSA surgeries available, other OSA surgical technologies are emerging and under investigation.¹⁻²

Medical Necessity Criteria

Indications

- The following **obstructive sleep apnea surgeries** are not considered appropriate, as they are clinically unproven and not medically necessary. There is inconclusive evidence of the effectiveness of **ANY** of the following procedures:
- ◆ Tongue base suspension with permanent suture technique³; **OR**
 - ◆ Submucosal radiofrequency ablation of the tongue base⁴⁻⁵; **OR**
 - ◆ Uvullectomy as a stand-alone procedure; **OR**
 - ◆ Insertion of implants into the soft palate (Pillar procedure)⁵⁻⁶; **OR**
 - ◆ OSA surgery in the absence of OSA diagnosis (e.g., snoring alone)⁴⁻⁵; **OR**
 - ◆ Laser-assisted uvulopalatoplasty (LAUP).^{5,7-8}

Non-Indications

→ **Obstructive sleep apnea surgeries (non-covered procedures)** are not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
41512	Tongue base suspension, permanent suture technique
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
42140	Uvulectomy, excision of uvula
C9727	Insertion of implants into the soft palate; minimum of three implants
S2080	Laser-assisted uvulopalatoplasty (LAUP)

Medical Evidence

Aurora et al. (2010) developed practice parameters for surgical modifications of the upper airway for obstructive sleep apnea in adults for the American Academy of Sleep Medicine (AASM). In this systematic review, the group recommended diagnosis of sleep apnea before initiating surgery, and included discussion of procedures such as tracheostomy, maxillo-mandibular advancement (MMA), laser-assisted uvulopalatoplasty (LAUP), uvulopalato-pharyngoplasty (UPPP), radiofrequency ablation (RFA), and palatal implants. UPPP as a sole procedure does not reliably normalize the apnea-hypopnea index (AHI) in moderate to severe OSA syndrome. LAUP was not recommended due to low-quality published evidence. LAUP usually does not normalize the AHI and no support was found in the literature for improvement in secondary outcomes. Additionally, the possibility of OSA symptom worsening exists. Very low quality evidence (case series and only one randomized controlled trial) exists to support the use of radiofrequency ablation, and long-term sequelae of RFA use were not published. The group concluded that there is a lack of rigorous data evaluating outcome measures and which populations would benefit from these surgical treatments. Palatal implants were described as an emerging treatment based on very low quality evidence. The group stated that it is difficult to predict if it will ultimately be found to be a reliably effective treatment option.⁵

Khasawneh et al. (2021) conducted a small study of 30 patients who underwent pillar implants for treatment of snoring and excessive daytime sleepiness. Limitations of the study included, in addition to the small study size, a lack of placebo controls due to the inappropriate nature of sham studies. Follow-up sleep studies were not conducted on all study participants due to cost constraints. Additionally, many of the study participants did not undergo polysomnography, and several participants experienced snoring as their only symptom. Longer term, larger studies were stated to be needed to predict long-term efficacy.⁶

Littner et al. (2001) reviewed the evidence for laser-assisted uvulopalatoplasty (LAUP) as the basis for the development of a practice parameter for the American Academy of Sleep Medicine (AASM). The group stated that

adequate controlled studies for LAUP were not found in peer-reviewed journals. This agreed with AASM's 1994 practice parameters for LAUP, and the group maintained their non-recommendation for LAUP as a treatment for sleep-related breathing disorders. The parameter does state that LAUP may be comparable to uvulopalatopharyngoplasty (UPPP) for the treatment of snoring.⁷

Camacho and colleagues (2017) published a systematic review and meta-analysis regarding laser-assisted uvulopalatoplasty (LAUP) for obstructive sleep apnea (OSA) treatment involving 717 patients in 23 studies of adult patients. This meta-analysis was based on case series analysis only without controls. The group found a 32% reduction in apnea-hypopnea index (AHI) although the lowest oxygen saturation (LSAT) only minimally changed. The individual data found a success rate of 23%, a cure rate of 8%, and 44% of patients experienced a worsening of AHI. LAUP was recommended by the group to be performed with caution or not at all based on the unfavorable results of the currently published studies.⁸

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) has published position statements including the following:

- **Tongue suspension** (Published 2012, Updated 2016): The group states that unconvincing results in earlier studies may have been related to poor patient selection. The studies cited by the group appear to have low numbers of participants. The group concluded that tongue-based suspension can potentially be effective when part of a comprehensive approach in the medical and surgical management of symptomatic adult patients with moderate to severe OSA.⁹ There is a lack of robust clinical studies to validate the efficacy of this procedure otherwise.
- **Submucosal ablation of the tongue base for OSAS** (Published 2010, Updated 2012): This guideline cited a number of non-randomized studies with low numbers of participants. The group commented that the majority of patients studied were not morbidly obese and experienced mild to moderate OSA. The studies cited that compared ablation with CPAP found similar effectiveness of both therapies.¹⁰

No current, peer-reviewed studies were found to support the use of uvulectomy as a stand-alone procedure for the treatment of obstructive sleep apnea.

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<https://www.entnet.org>.

Clinical Guideline Revision History/Information

Original Date: February 13, 2025		
Review History		



Cohere Medical Policy – Obstructive Sleep Apnea Surgeries

Clinical Policy for Medical Necessity Review

Version: 2

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Important Notices

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Policy Information:

Specialty Area: Sleep Medicine

Policy Name: Cohere Medical Policy - Obstructive Sleep Apnea Surgeries

Policy Number: CHP-034-2

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Obstructive Sleep Apnea Surgeries

Cohere Health takes an evidence-based approach to reviewing sleep medicine diagnostic testing, durable medical equipment (DME), and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior sleep testing, and details of previous treatments. Sleep medicine diagnostic testing, DME, and procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- Repeat sleep testing due to technical issues—such as signal artifact or loss of signal—may not be considered medically necessary, as it is the responsibility of the sleep testing center to deliver appropriate, high-quality studies as originally authorized. Similarly, repeat sleep testing requested at a different facility based solely on provider preference may not be approved for medical necessity.
- When multiple sleep tests are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.

- Why prior sleep tests were inconclusive, or why additional/follow-up studies are needed.
- How the results will impact patient management or treatment decisions.

Description

Obstructive sleep apnea (OSA) is characterized by repeated episodes of partial or complete upper airway closure during sleep, leading to pauses in breathing (apnea or hypopnea [lasting more than 10 seconds]). These episodes may result in brief awakenings or rapid breathing. OSA affects both adults and children and requires diagnostic testing for confirmation. While non-surgical treatments such as positive airway pressure (PAP) and oral appliances are available, surgery may be recommended due to suboptimal adherence and to reduce the risk of serious complications, including hypertension, atrial fibrillation, and heart failure, caused by intermittent oxygen deprivation.¹⁻⁴

Medical Necessity Criteria

Indications

Obstructive sleep apnea (OSA) surgeries are considered appropriate if **ALL** of the following are **TRUE**:

- **ANY** of the following procedures:
 - Hyoid myotomy and suspension^{5,6}; **OR**
 - Maxillomandibular osteotomy and advancement (MMA)^{3,7-9}; **OR**
 - Mandibular osteotomy (MO)^{7,8}; **OR**
 - Uvulopalatopharyngoplasty (UPPP)^{3,8,10}; **AND**
- Confirmed OSA diagnosis^A and **ANY** of the following^{7,11}:
 - Apnea-hypopnea index (AHI) greater than 15 (moderate to severe OSA)^{3,12}; **OR**
 - AHI from 5 to 15 (mild OSA) with additional diseases or conditions (e.g., hypertension, cardiovascular disease, excessive daytime sleepiness [EDS])^{3,12}; **AND**
- Documentation of anatomic abnormalities (e.g., palatal, nasal, lingual, or dental) by examination, endoscopy, or imaging⁴; **AND**

- Skeletal maturity has been reached, or the patient is 18 years of age or greater¹³; **AND**
- Documented failure or intolerance of positive airway pressure (PAP) therapy (e.g., persistent apnea or choking during sleep, claustrophobia, noise or pressure intolerance).^{9,10,14-17}

Non-Indications

Obstructive sleep apnea surgeries are not considered appropriate if **ANY** of the following is **TRUE**:

- Distraction osteogenesis for maxillary expansion (DOME)¹⁸; **OR**
- Insertion of implants into the soft palate (Pillar procedure)^{7,19}; **OR**
- Isolated hyoid myotomy; **OR**
- Laser-assisted uvulopalatoplasty (LAUP)^{7,20,21}; **OR**
- Lingual suspension^{B,22}; **OR**
- Radiofrequency ablation of the soft palate and/or tongue base^{3,7,10,23}; **OR**
- Transoral robotic surgery (TORS)²⁴; **OR**
- Uvulectomy as a stand-alone procedure; **OR**
- No diagnosis of OSA (e.g., snoring alone).

Definitions and Notes

^A Obstructive sleep apnea (OSA) diagnosis: OSA diagnosis has been confirmed by a physician specializing in sleep disorders by polysomnography in a facility-based laboratory or with a home-based study using a technically adequate device under the supervision of a physician specializing in sleep disorders.²⁵

^B Lingual suspension may also be referred to as tongue stabilization, tongue stitch, or tongue fixation.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
21685	Hyoid myotomy and suspension
41512	Tongue base suspension, permanent suture technique
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
42140	Uvulectomy, excision of uvula
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
42950	Pharyngoplasty (plastic or reconstructive operation on pharynx)
C9727	Insertion of implants into the soft palate; minimum of three implants
S2080	Laser-assisted uvulopalatoplasty (LAUP)

Medical Evidence

Khasawneh et al. (2021) conducted a small, prospective pretest-posttest study evaluating 30 patients who underwent pillar implants for the treatment of snoring and excessive daytime sleepiness. At 12-month follow-up, no change in snoring frequency per week was observed (6.9 versus 5.5; $P < 0.03$), but Epworth Sleepiness Scale (ESS) significantly improved (7.4 versus 5.9; $P < 0.01$). Limitations of the study included a small study size, heterogeneity in baseline symptoms (e.g., several patients experienced snoring as their only symptom), lack of a control group, and inconsistent follow-up sleep studies across patients. Authors noted a need for larger studies with longer follow-up duration to inform long-term efficacy.¹⁹

Lichien et al. (2021) conducted a systematic review and meta-analysis evaluating transoral robotic surgery (TORS) for the base of the tongue (BOT) in patients with obstructive sleep apnea (OSA). A total of 31 studies (22 retrospective, 8 prospective uncontrolled, and 1 randomized controlled trial [RCT]), including 1693 patients, were analyzed. Overall, the apnea-hypopnea index (AHI) decreased by 24.25 (95% CI, 21.69–26.81) events per hour following TORS BOT, and the ESS decreased by 7.92 (95% CI, 6.50–9.34) points. However, the authors noted several limitations, including predominantly retrospective study designs, heterogeneity in patient selection criteria and surgical technique, and the lack of standardized definitions for complications. They concluded that future prospective, controlled studies with longer follow-up are needed to confirm the effectiveness of TORS BOT.²⁴

No current, comparative, peer-reviewed studies were found that support the use of distraction osteogenesis for maxillary expansion (DOME) for OSA. Additional well-designed studies with control groups and long-term follow-up are needed to establish the effectiveness and safety of the procedure. Yoon et al. (2020) conducted a retrospective pretest-posttest study evaluating 75 adult patients undergoing DOME for OSA. Results suggest DOME significantly reduced mean AHI (pretest: 17.65 ± 19.30 ; posttest: 8.17 ± 8.47 ; $P < 0.0001$) and ESS (pretest: 10.48 ± 5.4 ; posttest: 6.69 ± 4.75 , $P < 0.0001$). No serious adverse events were identified. Study limitations included a small sample size,

retrospective design, lack of a comparator group, and lack of a consistent follow-up time point.¹⁸

Camacho and colleagues (2017) published a systematic review and meta-analysis assessing laser-assisted uvulopalatoplasty (LAUP) for OSA treatment. Twenty-three studies (2 RCTs and 21 prospective case series) with 717 adult patients were included. A 32% reduction in AHI was observed following LAUP. However, the lowest oxygen saturation (LSAT) did not significantly change posttreatment. The individual data found a success rate of 23%, a cure rate of 8%, and 44% of patients experienced a worsening of AHI. Authors stated that LAUP should be performed with caution or not at all based on the unfavorable results of the currently published studies.²¹

Ong et al. (2017) conducted a retrospective case series including 19 patients who underwent hyoid myotomy and suspension (HMS) without concurrent palatal or tongue base sleep surgery. The majority of patients (13 of 19; 68%) initially presented with an AHI greater than 30, indicating severe sleep apnea. Following the procedure, mean AHI significantly improved from 39.7 to 22.6. Surgical success, defined as a greater than 50% reduction in AHI and postoperative AHI less than 20 events per hour, was achieved in 47.4% of patients (9 of 19). No improvement in the ESS was observed.⁶

No current, peer-reviewed studies were found to support the use of uvulectomy as a stand-alone procedure for the treatment of obstructive sleep apnea.

The American Academy of Sleep Medicine (AASM) published a 2021 guideline for referral of adults with OSA for surgical consultation. The committee concluded with a strong recommendation that patients with OSA and a body mass index greater than 40 kg/m², when unaccepting or intolerant of PAP therapy, be referred to a sleep surgeon. A strong recommendation was given for discussion of referral to a bariatric surgeon for adults with OSA and body mass index (BMI) greater than 35 kg/m². Conditional recommendations were given for sleep surgeon referrals for adults with OSA and BMI less than 40 kg/m² with inadequate PAP adherence due to side effects and a PAP trial as initial therapy in adults with OSA and a major upper airway anatomic abnormality prior to surgical consult.¹⁰

The American Academy of Otolaryngology–Head and Neck Surgery (AAO–HNS) has published position statements, including the following:

- **Tongue suspension** (Published 2012, Updated 2016): The group states that unconvincing results in earlier studies may have been related to poor patient selection. The studies cited by the group appear to have small sample sizes. The group concluded that tongue-based suspension can potentially be effective when part of a comprehensive approach in the medical and surgical management of symptomatic adult patients with moderate to severe OSA.²² There is a lack of robust clinical studies to validate the efficacy of this procedure otherwise.
- **Submucosal ablation of the tongue base for OSAS** (Published 2010, Updated 2012): This position statement cited a number of non-randomized studies with low numbers of participants. The AAO–HNS commented that the majority of patients studied were not morbidly obese and experienced mild to moderate OSA. The cited studies comparing ablation with CPAP found that both therapies were similarly effective.²³

In 2010, the AASM developed practice parameters for surgical modifications of the upper airway in adults with OSA. The AASM stated that OSA must be diagnosed prior to initiating surgical therapy. Maxillomandibular advancement (MMA) was recommended for patients with severe OSA who are intolerant or refuse positive airway pressure therapy.

Uvulopalatopharyngoplasty (UPPP) alone was noted not to reliably normalize the apnea-hypopnea index (AHI) in moderate to severe OSA, and laser-assisted uvulopalatoplasty (LAUP) was not routinely recommended. The AASM also reported limited, very low-quality evidence supporting radiofrequency ablation (RFA) and palatal implants, but emphasized the need for additional studies to better define outcome measures and appropriate patient populations.⁷

In 2001, the AASM published a practice parameter on the use of laser-assisted uvulopalatoplasty (LAUP) for treatment of sleep-related breathing disorders. The AASM noted a lack of adequate controlled studies for LAUP in peer-reviewed journals. This agreed with AASM's 1994 practice parameters for LAUP, and AASM maintained their non-recommendation for LAUP as a treatment for sleep-related breathing disorders. The parameter does state

that LAUP may be comparable to uvulopalatopharyngoplasty (UPPP) for the treatment of snoring.²⁰

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Clinical Guideline Revision History/Information

Original Date: February 13, 2025		
Review History		
Version 2	02/26/2026	Annual review. Merged with previously titled “Cohere Medical Policy – Obstructive Sleep Apnea Surgeries (Non-Covered Procedures)”. Added indications “maxillomandibular osteotomy and advancement (MMA)” and “mandibular osteotomy (MO)”. Added non-indications “distraction osteogenesis for maxillary expansion (DOME)”, “isolated hyoid myotomy”, “lingual suspension”, and “transoral robotic surgery”. No changes to procedure codes. Expanded the Medical Evidence section; added 2 citations. Added references 18, 24.



Cohere Medicare Advantage Policy – Oral Appliance Therapy for Obstructive Sleep Apnea (OSA)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: February 13, 2025

Important Notices

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Guideline Information:

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Medical Necessity Criteria

Service: Oral Appliance Therapy for Obstructive Sleep Apnea (OSA)

Benefit Category

Not Applicable

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹

- [Local Coverage Determination \(LCD\). Oral appliances for obstructive sleep apnea \(L33611\)](#)

Recommended Clinical Approach

Oral appliance therapy is a non-invasive treatment for patients who have been diagnosed with obstructive sleep apnea (OSA). These patients may not have been successful with positive airway pressure (PAP) therapy due to intolerance or noncompliance. Customized for the patient, oral appliances for OSA treatment include mandibular advancement or tongue retraining devices.² Oral appliances for OSA treatment should be fitted, adjusted, and monitored by an otolaryngologist or a qualified dentist with sleep medicine training.³⁻⁵ The United States Food and Drug Administration (FDA) granted approval for the following devices for the treatment of obstructive sleep apnea (OSA): True Function Adjustable Herbst Appliance (2017), Narval CC (2011), and TAP II (2006).⁶⁻⁸

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of oral appliance therapy for obstructive sleep apnea (OSA). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- A 2019 report by the US Veterans Administration/Department of Defense identified risks of oral appliance therapy use for the treatment of mild to moderate OSA. Patients with unstable dentition, morbid obesity, and serious cardiovascular or pulmonary disorders may be better suited for PAP therapy. Side effects include pain in the teeth or jaws, change in bite, or movement of the teeth.⁹
- Several medical society guidelines, including those from the American Academy of Sleep Medicine (AASM) and the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), recommend that PAP therapy be tried and failed before oral appliance therapy can be initiated. This recommendation or requirement can delay treatment for patients who may have been successfully treated with oral appliance therapy.¹⁰⁻¹¹
- Johal et al. (2023) state that while PAP therapy is the “gold standard” treatment for OSA, oral appliance therapy is a recognized alternative treatment. Patients who are nonadherent with or of PAP therapy may be more successful with oral appliance therapy and therefore reduce the potentially dangerous physical and mental effects of OSA.¹²
- Increased healthcare costs and complications from the inappropriate use of OSA-related services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. In 2022, the American Academy of Dental Sleep Medicine (AADSM) released a standards for practice document supporting the use of oral appliance therapy in sleep-related breathing disorders. While not recommended as a first-line treatment for any level of severity of OSA, they state that it may be useful when other therapies have been attempted and have failed. They confirm that studies have shown oral appliance therapy is comparable to PAP therapy in reducing symptoms such as daytime sleepiness and hypertension, and is strongly preferred by many patients.¹³
- Potential to mitigate the risk of morbidity from OSA which may otherwise have gone untreated.

- Reduction in complications and adverse effects from unnecessary procedures. Skalna et al. (2019) studied oral appliance effectiveness and patient satisfaction with a patient enrollment of 58 adults (40 men and 18 women with a mean age of 50.5 years). The majority were overweight with a mean baseline AHI of 31.3. These patients were stated to have been intolerant to PAP therapy. 86% of patients experienced a reduction in AHI value, within a range of 5 to 25 AHI units. Positive responses regarding device effectiveness were recorded in 76.5% of patients. The majority of these patients wore the appliance nightly. Patient satisfaction was found to have similar percentages.¹⁴

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Oral appliance therapy for obstructive sleep apnea (OSA)** with a custom-fabricated mandibular advancement oral appliance (E0486) is considered appropriate if **ANY** of the following is **TRUE**^{1,15}:

◆ **ALL** of the following:

- The patient has an in-person clinical evaluation by the treating practitioner prior to the sleep test to assess the patient for OSA testing; **AND**
- The patient has a Medicare-covered sleep test that results in **ANY** of the following^{1,10-11}:
 - The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; **OR**

- The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of **ANY** of the following:
 - ◆ Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **OR**
 - ◆ Hypertension, ischemic heart disease, or history of stroke; **OR**
- The AHI or RDI is greater than 30 and **ANY** of the following:
 - ◆ The patient is not able to tolerate a positive airway pressure (PAP) device; **OR**
 - ◆ The treating practitioner determines that the use of a PAP device is contraindicated; **AND**
- The oral appliance is ordered by the treating practitioner following a review of the report of the sleep test*; **AND**
- The ordering appliance is provided and billed for by a licensed dentist (DDS or DMD)^{1, 9, 13}; **OR**
- ◆ Replacement of an oral appliance for OSA for **ANY** of the following:
 - Change in structure of the patient's oral cavity or teeth; **OR**
 - The appliance is worn due to excessive use and unable to be repaired; **OR**
 - The appliance has reached a 5-year reasonable useful lifetime (RUL).

***NOTE:** The treating practitioner should be different from the practitioner who initially evaluated the patient for OSA.

Non-Indications

- **Oral appliance therapy for obstructive sleep apnea** is not considered appropriate if **ANY** of the following is **TRUE**¹:
- ◆ The criteria listed in the Indications section above have not been met; **OR**
 - ◆ A prefabricated oral appliance (E0485) has been ordered for the patient^{1, 15}; **OR**
 - ◆ Replacement of an oral appliance in cases of misuse or abuse.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Johal et al. (2023) state that while PAP therapy is the “gold standard” treatment for OSA, oral appliance therapy is a recognized alternative treatment. Patients who are nonadherent with or intolerant of PAP therapy may be more successful with oral appliance therapy and therefore reduce the effects of OSA. In this systematic review, the writing group examined the treatment outcomes of patients with custom-made, titratable intra-oral appliances. These were found to influence patient preferences and adherence. It was noted that prefabricated appliances are not favorable as they cannot adapt to various oral anatomies. Early discontinuation (less than 2 years of usage) of the device by patients was generally related to pain or discomfort, and occurred more often with prefabricated devices.¹²

Trzepizur et al. (2021) conducted a meta-analysis of several RCTs that included 249 adult patients with severe OSA to study the effects of CPAP and titratable mandibular advancement devices (MADs). Study participants had been diagnosed with severe OSA based on an AHI of greater than 30 per hour. MADs used in the trial were required to be custom-made with progressive titration. The authors found that titratable MADs produced similar results to PAP related to patient sleepiness and quality of life; however, PAP therapy was more effective in reducing apnea/hypopnea index (AHI). Overall, the study concluded that there were no statistically significant differences related to sleepiness and sleep architecture when MAD and CPAP were compared. Patient preference was higher with MAD resulting in increased adherence to treatment.¹⁶

Ou et al. (2024) reported on CRESCENT (Cardiosleep Research Program on Obstructive Sleep Apnea, Blood Pressure Control and Maladaptive Myocardial Remodeling—Non-inferiority Trial). The randomized control trial (RCT) on the efficacy of mandibular advancement device (MAD) versus continuous positive airway pressure (CPAP) to reduce ambulatory blood pressure. A total of 220 participants aged 40 years or older were identified; two-thirds had severe obstructive sleep apnea (OSA) and were at-risk for developing cardiovascular disease. Participants were randomly assigned to either the MAD or CPAP group. A greater reduction in secondary ambulatory blood

pressure parameters was identified in the MAD group however, both groups demonstrated improvement in daytime sleepiness.¹⁷

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Cohere Medical Policy – Oral Appliance Therapy for Obstructive Sleep Apnea (OSA)

Clinical Guidelines for Medical Necessity Review

Version: 1
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Important Notices

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Guideline Information:

Specialty Area: Sleep Medicine

Guideline Name: Cohere Medical Policy – Oral Appliance Therapy for Obstructive Sleep Apnea (OSA)

Date of last literature review: 02/10/2025

Document last updated: 02/12/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Oral Appliance Therapy for Obstructive Sleep Apnea (OSA)

Recommended Clinical Approach

Oral appliance therapy is a non-invasive treatment for patients who have been diagnosed with obstructive sleep apnea (OSA). These patients may not have been successful with positive airway pressure (PAP) therapy due to intolerance or noncompliance. Customized for the patient, oral appliances for OSA treatment include mandibular advancement or tongue retraining devices.¹ It is recommended that oral appliances for OSA treatment be fitted, adjusted, and monitored by an otolaryngologist or a qualified dentist with sleep medicine training.²⁻⁴ The United States Food and Drug Administration (FDA) granted approval for the following devices for the treatment of obstructive sleep apnea (OSA): True Function Adjustable Herbst Appliance (2017), Narval CC (2011), and TAP II (2006).⁵⁻⁷

Medical Necessity Criteria

Indications

→ **Oral appliance therapy for obstructive sleep apnea (OSA)** is considered appropriate if **ANY** of the following are **TRUE**:

◆ **Adult patients** 18 years of age or older and **ALL** of the following:

- The patient has a confirmed diagnosis* of OSA⁸⁻⁹; **AND**
- The patient has undergone a complete intra-oral and dental examination¹⁰; **AND**
- The oral appliance has been custom-made for the patient^{9, 11-13}; **AND**
- **ANY** of the following:
 - **ALL** of the following:
 - ◆ Apnea-hypopnea index (AHI) less than 15 (mild to moderate OSA)⁹; **AND**
 - ◆ Documented failure or intolerance of positive airway pressure (PAP) therapy (e.g., oropharyngeal anatomic abnormalities, persistent apnea or choking during sleep,

- claustrophobia, noise or pressure intolerance)⁹
¹²; **OR**
 - The AHI or RDI is greater than 30 and **ANY** of the following⁹:
 - ◆ The patient is not able to tolerate a positive airway pressure (PAP) device; **OR**
 - ◆ The treating practitioner determines that the use of a PAP device is contraindicated; **OR**
 - ◆ **Pediatric patients** younger than 18 years of age with craniofacial anomalies and signs and symptoms of OSA¹⁴⁻¹⁵; **OR**
 - ◆ Replacement of an oral appliance for OSA for **ANY** of the following:
 - Change in structure of the patient's oral cavity or teeth; **OR**
 - The appliance is worn due to excessive use and unable to be repaired; **OR**
 - The appliance has reached a 5-year reasonable useful lifetime (RUL).

* NOTE: OSA diagnosis has been confirmed by a physician specializing in sleep disorders by polysomnography in a facility-based laboratory or with a home-based study using a technically adequate device under the supervision of a physician specializing in sleep disorders.¹⁶

Non-Indications

- **Oral appliance therapy for obstructive sleep apnea (OSA)** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ PAP has not been attempted⁸⁻⁹; **OR**
 - ◆ The patient does not have adequate dentition to support the device¹⁷; **OR**
 - ◆ The patient has temporomandibular joint disease¹⁷; **OR**
 - ◆ The patient has a seizure disorder¹¹; **OR**
 - ◆ Replacement of an oral appliance in cases of misuse or abuse.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

Medical Evidence

Ou et al. (2024) reported on CRESCENT (Cardiosleep Research Program on Obstructive Sleep Apnea, Blood Pressure Control and Maladaptive Myocardial Remodeling—Non-inferiority Trial). The randomized control trial (RCT) on the efficacy of mandibular advancement device (MAD) versus continuous positive airway pressure (CPAP) to reduce ambulatory blood pressure. A total of 220 participants aged 40 years or older were identified; two-thirds had severe obstructive sleep apnea (OSA) and were at-risk for developing cardiovascular disease. Participants were randomly assigned to either the MAD or CPAP group. A greater reduction in secondary ambulatory blood pressure parameters was identified in the MAD group however, both groups demonstrated improvement in daytime sleepiness.¹⁸

Trzepizur et al. (2021) conducted a meta-analysis of several RCTs that included 249 adult patients with severe OSA to study the effects of CPAP and titratable mandibular advancement devices (MADs). Study participants had been diagnosed with severe OSA based on an AHI of greater than 30 per hour. MADs used in the trial were required to be custom-made with progressive titration. The authors found that titratable MADs produced similar results to PAP related to patient sleepiness and quality of life; however, PAP therapy was more effective in reducing apnea/hypopnea index (AHI). Overall, the study concluded that there were no statistically significant differences related to sleepiness and sleep architecture when MAD and CPAP were compared. Patient preference was higher with MAD resulting in increased adherence to treatment.¹⁹

Johal et al. (2023) state that while PAP therapy is the “gold standard” treatment for OSA, oral appliance therapy is a recognized alternative treatment. Patients who are noncompliant or nontolerant with PAP therapy may be more successful with oral appliance therapy and therefore reduce the potentially dangerous physical and mental effects of OSA. In this systematic review, the writing group examined the treatment outcomes of patients with custom-made, titratable intra-oral appliances. These were found to influence patient preferences and adherence. It was noted that prefabricated appliances are not favorable as they cannot adapt to various oral anatomies. Early discontinuation was found to be less than 2 years and

generally related to pain or discomfort, and more often with prefabricated devices.²⁰

Skalna et al. (2019) studied oral appliance effectiveness and patient satisfaction with a patient enrollment of 58 adults (40 men and 18 women with a mean age of 50.5 years). The majority were overweight with a mean baseline AHI of 31.3. These patients were stated to have been intolerant to PAP therapy. 86% of patients experienced a reduction in AHI value, within a range of 5 to 25 AHI units. Positive responses regarding device effectiveness were recorded in 76.5% of patients. The majority of these patients wore the appliance nightly. Patient satisfaction was found to have similar percentages, resulting in enhanced overall patient satisfaction and healthcare experience.²¹

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Cohere Medicare Advantage Policy – Positive Pressure Ventilation

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Sleep Medicine

Policy Name: Cohere Medicare Advantage Policy - Positive Pressure Ventilation

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Positive Pressure Ventilation

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁸

- [National Coverage Determination. Noninvasive positive pressure ventilation \(NIPPV\) in the home for the treatment of chronic respiratory failure \(CRF\) consequent to chronic obstructive pulmonary disease \(COPD\) \(240.9\)](#)
- [Medicare Claims Processing. Noninvasive positive pressure ventilation \(NIPPV\) in the home for the treatment of chronic respiratory failure \(CRF\) consequent to chronic obstructive pulmonary disease \(COPD\) \(Publication 100-04\).](#)
- [Local Coverage Determination \(LCD\). Positive airway pressure \(PAP\) devices for the treatment of obstructive sleep apnea \(L33718\)](#)
 - [Policy Article: Positive airway pressure \(PAP\) devices for the treatment of obstructive sleep apnea \(A52467\)](#)
- [Local Coverage Determination \(LCD\). Respiratory assist devices \(L33800\)](#)
 - [Policy Article: Respiratory assist devices \(A52517\)](#)
- [Local Coverage Determination \(LCD\). Respiratory care \(L34149\)](#)
 - [Billing and Coding: Respiratory care \(A57224\)](#)

Description

Positive pressure ventilation (PPV) or positive airway pressure (PAP) is delivered using a tight-fitting mask that covers the patient's nose or both the nose and mouth. PPV or PAP is administered via continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP), or bilevel positive airway pressure (BiPAP). CPAP is used to treat obstructive sleep apnea (OSA); BiPAP is used for patients with conditions such as OSA, COPD, and obesity-hypoventilation syndrome (OHS).⁹

Medical Necessity Criteria

Indications

Positive pressure ventilation (PPV) is considered appropriate if **ANY** of the following is **TRUE**:

- For continuous positive airway pressure (CPAP) or automatic positive airway pressure (APAP) with **ANY** of the following:
 - Obstructive sleep apnea (OSA)* in persons aged 18 years or older for an FDA-approved diagnostic sleep test (type I, II, III, IV, other)³ with **ANY** of the following¹⁰⁻¹²:
 - Apnea hypopnea index (AHI) or respiratory event index (REI) is **ANY** of the following¹³:
 - 5–14.9 events per hour (mild OSA) with a condition and/or symptoms (e.g., cardiovascular, metabolic, renal, pulmonary, neuropsychiatric) with **ANY** of the following^{3,14}:
 - Excessive daytime sleepiness; **OR**
 - Impaired cognition; **OR**
 - Mood disorders; **OR**
 - Insomnia; **OR**
 - Hypertension; **OR**
 - Ischemic heart disease; **OR**
 - History of stroke; **OR**
 - 15–29.9 events per hour (moderate OSA)^{3,15}; **OR**
 - Greater than or equal to 30 events per hour (severe OSA)¹⁵; **OR**
 - Preoperative preparation that is intended to improve or optimize the patient's perioperative physical status¹⁶; **OR**
 - OSA* in persons aged 1–17 years with **ALL** of the following:
 - AHI or REI is **ANY** of the following¹⁷⁻¹⁸:
 - 1–4 events per hour (mild OSA) with a condition and/or symptoms (e.g., cardiovascular, metabolic, renal, pulmonary, neuropsychiatric); **OR**
 - 5–9 events per hour (moderate OSA); **OR**
 - 10 or more events per hour (severe OSA); **AND**
 - **ANY** of the following:
 - Persistent OSA and the patient does not qualify for site-specific upper airway treatment¹⁹; **OR**
 - Persistent OSA with **ANY** of the following²⁰:

- Post-adenotonsillectomy; **OR**
- Frequent snoring (3 times or more per week); **OR**
- Labored breathing during sleep; **OR**
- Gasps, snorting noises, or observed episodes of apnea; **OR**
- Sleep enuresis (especially secondary enuresis) following at least 6 months of continence; **OR**
- Sleeping in a seated position or with the neck hyperextended; **OR**
- Cyanosis; **OR**
- Headaches on awakening; **OR**
- Daytime sleepiness; **OR**
- Attention deficit hyperactivity disorder (ADHD); **OR**
- Learning problems; **OR**
- Underweight or overweight; **OR**
- Tonsillar hypertrophy; **OR**
- Adenoidal facies; **OR**
- Micrognathia/retrognathia; **OR**
- High-arched palate; **OR**
- Failure to thrive; **OR**
- Hypertension; **OR**
- Upper airway resistance syndrome (UARS) with **ALL** of the following:
 - A CPAP device is to be used nightly²¹; **AND**
 - **ALL** of the following²²:
 - AHI less than 5 events per hour; **AND**
 - A minimum SpO₂ of greater than or equal to 92%, the presence of airflow limitation during sleep for greater than or equal to 5% of total sleep time; **AND**
 - Daytime sleepiness and/or fatigue; **OR**
- For bilevel positive airway pressure (BiPAP) with **ANY** of the following:
 - Failure of CPAP with **ANY** of the following:
 - The device is uncomfortable; **OR**
 - The patient is intolerant; **OR**
 - The patient has a contraindication; **OR**
 - CPAP was ineffective; **OR**
 - **ANY** of the following:
 - Central sleep apnea (CSA) with **ALL** of the following²³:
 - Significant improvement of the sleep-associated hypoventilation is expected with the use of a respiratory assist device on the

settings that will be prescribed for initial use at home while breathing the beneficiary's prescribed FIO2⁵; **AND**

- **ANY** of the following:
 - CSA is related to congestive heart failure (CHF); **OR**
 - Initial treatment with CPAP therapy is to normalize the apnea-hypopnea index (AHI); **AND**
- An adaptive servo-ventilation (ASV) device is to be used nightly²⁴; **OR**
- Chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease with **ALL** of the following¹⁻⁸:
 - An arterial blood gas PaCO2, done while awake and breathing the patient's prescribed FIO2, is greater than or equal to 52 mm Hg; **AND**
 - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to a cumulative 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient's prescribed FIO2 (whichever is higher); **AND**
 - Before initiating therapy, sleep apnea and treatment with a CPAP device have been considered and ruled out*; **AND**
 - A BiPAP device is to be used nightly; **OR**
- Hypoventilation syndrome with **ALL** of the following⁵:
 - An initial arterial blood gas PaCO2 greater than or equal to 45 mm Hg (done while awake and the patient is breathing prescribed FIO2); **AND**
 - Spirometry shows an FEV1/FVC greater than or equal to 70%; **AND**
 - **ANY** of the following:
 - An arterial blood gas PaCO2 (done during sleep or immediately upon awakening, and the patient is breathing prescribed FIO2) that shows the patient's PaCO2 worsened by greater than or equal to 7 mm Hg compared to the initial arterial blood gas result above; **OR**
 - A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events (i.e., AHI less than 5); **AND**

- For obesity hypoventilation syndrome (OHS), the patient meets **ANY** of the following:
 - For the initial treatment of a stable ambulatory adult patient with OHS²⁵; **OR**
 - Concurrent severe OSA (AHI greater than or equal to 30 events per hour) presenting with chronic stable respiratory failure; **AND**
- A BiPAP device is to be used nightly; **OR**
- Restrictive thoracic disorders (e.g., progressive neuromuscular disease, thoracic cage abnormality) with **ALL** of the following^{5,26}:
 - **ANY** of the following:
 - Chronic respiratory failure; **OR**
 - Sleep-related breathing disorders; **AND**
 - A BiPAP device is to be used nightly or more often as needed as the disease progresses; **AND**
 - **ANY** of the following⁵:
 - An arterial blood gas PaCO₂, done while awake and breathing the beneficiary's prescribed FIO₂ is greater than or equal to 45 mm Hg; **OR**
 - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the beneficiary's prescribed recommended FIO₂; **OR**
 - If the patient has neuromuscular disease, **ANY** of the following:
 - Maximal inspiratory pressure is less than 60 cm H₂O; **OR**
 - Forced vital capacity is less than 50% predicted; **OR**
 - COPD does not contribute significantly to the patient's pulmonary limitation⁵; **OR**
- Either a heated or non-heated humidifier is considered medically necessary for use with BiPAP or CPAP³⁻⁴; **OR**
- For continued coverage of BiPAP or CPAP beyond the initial 90-day period with **ALL** of the following:
 - Documentation stating that an in-person re-evaluation demonstrated improvement by the patient and continued use will likely provide additional improvement³; **AND**
 - The patient is compliant and uses the device for at least 4 or more hours a night for at least 70% of 30 consecutive nights^{3,27}; **AND**

- **ANY** of the following^{**}:
 - The current device is in proper working order, and the patient does not require another device; **OR**
 - Replacement of the current PAP device for **ANY** of the following³⁻⁴:
 - The PAP device has reached a 5-year reasonable useful lifetime (RUL)²⁸; **OR**
 - Repairs, maintenance, or replacement are not covered under a manufacturer's warranty; **OR**
 - Replacement of either a heated or non-heated humidifier for use with BiPAP or CPAP with **ANY** of the following:
 - Continued resolution of symptoms and improved AHI on PAP therapy; **OR**
 - Device consistently used greater than or equal to 4 hours per night on 70% of nights; **OR**
 - The humidifier device is not operating; **OR**
 - DME supplier has physically evaluated the device and determined that it cannot be repaired; **OR**
 - The device to be replaced is no longer covered under a warranty.

*NOTE: Formal sleep testing is not required if there is sufficient information in the medical record to demonstrate that the patient does not suffer from some form of sleep apnea (OSA, CSA) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation.⁴

**NOTE: The patient's plan determines whether a device should be rented or purchased. General guidance is that when the rental cost exceeds the cost to purchase a device, consideration shall be given to purchase the device. The total covered cost cannot exceed the purchase or rental price.

Non-Indications

Positive pressure ventilation (PPV) is not considered appropriate if **ANY** of the following is **TRUE**:

- A bi-level positive airway pressure device with back up rate (CPT E0471) if the primary diagnosis is OSA³; **OR**
- Current endotracheal intubation²⁹; **OR**
- Anticipated need for prolonged mechanical ventilation²⁹; **OR**
- Encephalopathy or altered mental status²⁹; **OR**

- Hemodynamic instability²⁹; **OR**
- Facial trauma or facial defects²⁹; **OR**
- Airway obstruction secondary to a mass²⁹; **OR**
- Gastrointestinal bleeding.²⁹

Definitions

Apnea Hypopnea Index (AHI): number of apneas and hypopneas per total sleep time.¹³

Respiratory Disturbance Index (RDI): number of apneas and hypopneas and respiratory effort-related arousals (RERAs) per total sleep time.¹³

Respiratory Event Index (REI): number of apneas and hypopneas per monitoring time.¹³

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0561	Humidifier, nonheated, used with positive airway pressure
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous positive airway pressure (CPAP) device

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of positive pressure ventilation (PPV). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Mask discomfort. While the incidence is high, mask adjustments or a new mask typically alleviate most discomfort. When there is a skin irritation or infection, topical steroids or antibiotics are prescribed.³⁰
- Neuromuscular issues. Khan et al. (2023) discussed respiratory muscle weakness as a main complication for patients with neuromuscular diseases. Complications may include breathing disorders that are sleep-related, nighttime hypoventilation, improper ventilation, and decreased ability to mobilize secretions (which may lead to death).²⁶
- Complications. In rare cases, hemodynamic compromise occurs. Corp et al. (2021) noted the impact of PPV on heart-lung interactions as well as “the longer-term impact of shear forces on lung tissue and inflammatory reactions secondary to mechanical ventilation and extrathoracic sequelae.”³¹
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes. Yeghiazarians et al. (2021) note that patients reported increased left ventricular function, less sympathetic tone, and myocardial oxygen consumption.¹⁰
- Avoidance of intubation. Positive pressure ventilation (PPV) with standard therapy for acute respiratory failure reduces the need for endotracheal intubation.³²
- Reduced hospitalization and mortality.^{10,33}
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Evidence

Patil et al. (2024) discuss a systematic review by the Agency for Healthcare Research and Quality (AHRQ) of long-term outcomes and obstructive sleep apnea (OSA). Patients who received CPAP therapy showed stronger, statistically significant associations between CPAP treatment for OSA and reduced all-cause mortality, which remained when analyses included randomized control trials (RCTs) and non-RCTs. The studies also address excessive daytime sleepiness (EDS), which can increase symptoms of OSA. Therapy with CPAP has short-term benefits, and symptoms return when treatment is discontinued. The American Academy of Sleep Medicine (AASM) conducted a systematic review and meta-analysis of 33 RCTs. Overall, there is a high level of evidence for CPAP therapy for patients with EDS; the AASM also strongly recommends CPAP therapy.³⁴

Masa et al. (2020) conducted an RCT on obesity hypoventilation syndrome (OHS) and cardiac dysfunction. The focus of the secondary analysis was the Pickwick Project, the largest multicenter RCT on OHS. A total of 196 patients with OHS and severe OSA were included; a 3-year timeframe was used to determine the efficacy of noninvasive ventilation (NIV) and CPAP. Of the patients, 102 received CPAP therapy, and 94 received NIV (two levels of pressure). Both therapies showed similar improvement, specifically left ventricular diastolic dysfunction and reduced left atrial diameter. Respiratory function and dyspnea also improved, thus demonstrating the efficacy of both CPAP and NIV. (ClinicalTrials.gov Identifier: NCT01405976).³⁵

Wang et al. (2019) investigated the use of noninvasive positive pressure ventilation (NIPPV) for adults with chronic respiratory failure due to chronic obstructive pulmonary disease (COPD), thoracic restrictive disorders (TRD), neuromuscular disease (NMD), and obesity hypoventilation syndrome (OHS). The systematic review included 68 studies with a total of 53,733 patients. For all conditions, NIPPV demonstrated a significant reduction in mortality (statistically and clinically). Patients with COPD demonstrated decreased hospitalizations, intubations, and dyspnea. Patients with TRD, NMD, OHS, and other lung diseases demonstrated increased exercise tolerance, quality of life, and sleep quality; dyspnea and hospitalizations decreased.³⁶

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Clinical Guideline Revision History/Information

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Version 2	12/18/2025	Revision. Per CMS updates: Added NCD 240.9. Added Publication 100-04 describing use of biPAP for chronic respiratory failure consequent to COPD. Added L34149, updated related links and reference for A57224. Updated links and reference for L33800- Added related Policy Article A52517. Clarified COPD criteria to include, "chronic respiratory failure consequent to COPD" Clarified intubation and ventilation bullets in non-indications.

Cohere Medical Policy – Positive Pressure Ventilation

Clinical Policy for Medical Necessity Review

CHP-092-3 Version 3

Cohere Health UMC Approval Date: May 7, 2026

Last Annual Review: May 7, 2026

Revision Date: Not applicable

Next Annual Review: May 7, 2027

Specialty: Sleep Medicine

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Procedure Codes (CPT/HCPCS)

Service: Positive Pressure Ventilation

Code	Description
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous positive airway pressure (cpap) device

Service: Continuation of CPAP or Bilevel Positive Airway Pressure

Code	Description
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0601	Continuous positive airway pressure (cpap) device

Service: Replacement CPAP or Bilevel Positive Airway Pressure Device

Code	Description
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0601	Continuous positive airway pressure (cpap) device

Service: Initial Heated and Non-Heated PAP Humidifier Set-up

Code	Description
E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Service: Positive Pressure Ventilation - Description

Positive pressure ventilation (PPV) can be delivered via noninvasive positive pressure ventilation (NIPPV) using a tight-fitting mask that covers the nose or both the nose and mouth. NIPPV may be administered using continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP), or bilevel positive airway pressure. CPAP is used to treat obstructive sleep apnea (OSA); bilevel positive airway pressure is used for patients with OSA and obesity-hypoventilation syndrome (OHS).¹

Service: Positive Pressure Ventilation - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing sleep medicine diagnostic testing, durable medical equipment (DME), and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior sleep testing, and details of previous treatments. Sleep medicine diagnostic testing, DME, and procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- Repeat sleep testing due to technical issues—such as signal artifact or loss of signal—may not be considered medically necessary, as it is the responsibility of the sleep testing center to deliver appropriate, high-quality studies as originally authorized. Similarly, repeat sleep testing requested at a different facility based solely on provider preference may not be approved for medical necessity.
- When multiple sleep tests are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior sleep tests were inconclusive, or why additional/follow-up studies are needed.
 - How the results will impact patient management or treatment decisions.

Indications

- **Positive pressure ventilation (PPV)** is considered appropriate if **ANY** of the following is **TRUE**:
 - **Continuous positive airway pressure (CPAP) or automatic positive airway pressure (APAP)** for obstructive sleep apnea (OSA) with **ANY** of the following²:
 - Age 18 years or older with **ANY** of the following^{3,4}:
 - Mild OSA demonstrated by **ALL** of the following:
 - ▲ Apnea hypopnea index (AHI) or respiratory event index (REI) greater than or equal to 5 and less than or equal to 14.9 events per hour; **AND**
 - ▲ Documented symptoms of **ANY** of the following⁵:
 - △ Excessive daytime sleepiness; **OR**
 - △ Hypertension; **OR**
 - △ History of stroke; **OR**
 - △ Impaired cognition; **OR**
 - △ Insomnia; **OR**
 - △ Ischemic heart disease; **OR**
 - △ Mood disorders; **OR**
 - Moderate to severe OSA demonstrated by AHI or REI greater than or equal to 15 events per hour⁶; **OR**
 - Age 1–17 years with **ALL** of the following:

- ☐ AHI is greater than 17⁹; **AND**
- ☐ Surgery is not performed, is contraindicated, or if OSA persists after surgery¹⁰; **OR**
- **Bilevel positive airway pressure** with **ANY** of the following:
 - Failure of CPAP due to **ANY** of the following:
 - ☐ Device is uncomfortable; **OR**
 - ☐ Ineffective treatment; **OR**
 - ☐ Patient is intolerant; **OR**
 - ☐ Presence of a contraindication; **OR**
 - **ANY** of the following:
 - ☐ Central sleep apnea (CSA)¹¹; **OR**
 - ☐ Chronic obstructive pulmonary disease (COPD) for **ANY** of the following¹²:
 - ▲ Initial bilevel positive airway pressure with **ALL** of the following:
 - △ Awake arterial blood gas (ABG) PaCO₂ of greater than or equal to 52 mm Hg on prescribed fraction of inspired oxygen (FiO₂); **AND**
 - △ OSA and treatment with a CPAP device have been considered and ruled out (formal sleep testing is not required); **AND**
 - △ **ANY** of the following:
 - ◆ No change in clinical symptoms or medications for 2 weeks; **OR**
 - ◆ Persistent hypercapnia (PaCO₂ of greater than or equal to 52 mm Hg) on ABG 2 weeks post-exacerbation; **OR**
 - ▲ Continued bilevel positive airway pressure after the initial 6-month period with **ALL** of the following:
 - △ Consistent device use of greater than or equal to 4 hours per night on 70% of nights within a 30-day period; **AND**
 - △ High intensity therapy with inspiratory positive airway pressure (IPAP) greater than or equal to 15 centimeters of water (cmH₂O) and respiratory rate at least 14 breaths per minute (bpm); **AND**
 - △ Improvement in clinical outcomes (e.g., normalization of CO₂, stabilization of rising CO₂) or clinical symptoms (e.g., fatigue, headache, shortness of breath, sleep quality, confusion); **AND**
 - △ Clinical evaluation every 6 months; **OR**
 - ☐ Hypoventilation syndrome with **ANY** of the following^{13,14}:
 - ▲ Persistent hypoxemia (peripheral oxygen saturation [SpO₂] less than 88% for at least 5 minutes) while using CPAP (greater than or equal to 4 hours per night on 70% of nights); **OR**
 - ▲ **ALL** of the following:
 - △ Facility-based polysomnography (PSG) or home sleep test demonstrates oxygen saturation less than or equal to 88% for at least 5 minutes of nocturnal recording time (minimum recording time of 2 hours); **AND**
 - △ **ANY** of the following:
 - ◆ Awake ABG PaCO₂, end-tidal PCO₂ (EtPCO₂), or transcutaneous PCO₂ (TcPCO₂) of greater than or equal to 45 mm Hg; **OR**
 - ◆ Venous blood gas (VBG) of greater than or equal to 50 mm Hg; **OR**
 - ◆ Serum bicarbonate of greater than or equal to 27; **OR**
 - ☐ Neuromuscular disease (e.g., amyotrophic lateral sclerosis) or severe thoracic cage abnormality (e.g., severe kyphoscoliosis, post-thoracoplasty) with **ANY** of the following¹⁵:
 - ▲ Vital capacity (forced or slow) less than or equal to 50% of predicted capacity; **OR**
 - ▲ Maximal inspiratory pressure of less than or equal to 60 cmH₂O; **OR**

- ▲ Awake ABG PaCO₂ of greater than or equal to 45 mm Hg on prescribed fraction of inspired oxygen (FiO₂); **OR**
- ▲ EtPCO₂ or TcPCO₂ or VBG of greater than or equal to 50 mm Hg; **OR**
- ▲ Sniff nasal inspiratory pressure of less than or equal to 40 cmH₂O; **OR**
- ▲ **ALL** of the following:
 - △ Symptoms including **ANY** of the following:
 - ◆ Daytime sleepiness; **OR**
 - ◆ Dyspnea; **OR**
 - ◆ Morning headache; **OR**
 - ◆ Orthopnea; **OR**
 - ◆ Unrefreshing sleep; **AND**
 - △ Vital capacity of less than 80%; **OR**
- ▲ Sleep oximetry or sleep testing demonstrates oxygen saturation including **ANY** of the following:
 - △ Less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time; **OR**
 - △ Less than or equal to 90% for greater than or equal to 5% of the night.

Non-Indications

- **Positive pressure ventilation (PPV)** is not considered appropriate if **ANY** of the following is **TRUE**¹⁶:
 - Airway obstruction secondary to a mass; **OR**
 - Anticipated need for prolonged mechanical ventilation; **OR**
 - Encephalopathy or altered mental status; **OR**
 - Facial trauma or facial defects; **OR**
 - Gastrointestinal bleeding; **OR**
 - Hemodynamic instability; **OR**
 - Need for intubation.

Service: Continuation of CPAP or Bilevel Positive Airway Pressure - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing sleep medicine diagnostic testing, durable medical equipment (DME), and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior sleep testing, and details of previous treatments. Sleep medicine diagnostic testing, DME, and procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- Repeat sleep testing due to technical issues—such as signal artifact or loss of signal—may not be considered medically necessary, as it is the responsibility of the sleep testing center to deliver appropriate, high-quality studies as originally authorized. Similarly, repeat sleep testing requested at a different facility based solely on provider preference may not be approved for medical necessity.
- When multiple sleep tests are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior sleep tests were inconclusive, or why additional/follow-up studies are needed.
 - How the results will impact patient management or treatment decisions.

Indications

- **Continuation of CPAP or bilevel positive airway pressure** is considered appropriate if **ANY** of the following is **TRUE**:
 - In the initial 90-day period with **ALL** of the following:
 - Documentation stating that a re-evaluation demonstrated improvement by the patient and continued use will likely provide additional improvement; **AND**
 - Consistent device use of greater than or equal to 4 hours per night on 70% of nights within a 30-day period; **OR**
 - Following the initial 90-day period, documentation stating that a re-evaluation demonstrated improvement by the patient and continued use will likely provide additional improvement.

Non-Indications

- **Positive pressure ventilation (PPV)** is not considered appropriate if **ANY** of the following is **TRUE**¹⁶:
 - Airway obstruction secondary to a mass; **OR**
 - Anticipated need for prolonged mechanical ventilation; **OR**
 - Encephalopathy or altered mental status; **OR**
 - Facial trauma or facial defects; **OR**
 - Gastrointestinal bleeding; **OR**
 - Hemodynamic instability; **OR**

- Need for intubation.

Service: Replacement CPAP or Bilevel Positive Airway Pressure Device - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing sleep medicine diagnostic testing, durable medical equipment (DME), and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior sleep testing, and details of previous treatments. Sleep medicine diagnostic testing, DME, and procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- Repeat sleep testing due to technical issues—such as signal artifact or loss of signal—may not be considered medically necessary, as it is the responsibility of the sleep testing center to deliver appropriate, high-quality studies as originally authorized. Similarly, repeat sleep testing requested at a different facility based solely on provider preference may not be approved for medical necessity.
- When multiple sleep tests are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior sleep tests were inconclusive, or why additional/follow-up studies are needed.
 - How the results will impact patient management or treatment decisions.

Indications

- **Replacement CPAP or bilevel positive airway pressure device** is considered appropriate if **ANY** of the following is **TRUE**:
 - Appliance has reached a 5-year reasonable use lifetime; **OR**
 - Sleep disordered breathing with **ALL** of the following:
 - Continues to provide sustained symptom and apnea hypopnea index (AHI)/respiratory disturbance index (RDI) improvement; **AND**
 - Consistent device use of greater than or equal to 4 hours per night on 70% of nights; **AND**
 - Device is not operating; **AND**
 - Durable medical equipment (DME) supplier has physically evaluated the device and determined that it cannot be repaired; **AND**
 - Device is no longer covered under a warranty.

Non-Indications

- **Positive pressure ventilation (PPV)** is not considered appropriate if **ANY** of the following is **TRUE**¹⁶:
 - Airway obstruction secondary to a mass; **OR**
 - Anticipated need for prolonged mechanical ventilation; **OR**
 - Encephalopathy or altered mental status; **OR**
 - Facial trauma or facial defects; **OR**

- Gastrointestinal bleeding; **OR**
- Hemodynamic instability; **OR**
- Need for intubation.

Service: Initial Heated and Non-Heated PAP Humidifier Set-up

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing sleep medicine diagnostic testing, durable medical equipment (DME), and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior sleep testing, and details of previous treatments. Sleep medicine diagnostic testing, DME, and procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- Repeat sleep testing due to technical issues—such as signal artifact or loss of signal—may not be considered medically necessary, as it is the responsibility of the sleep testing center to deliver appropriate, high-quality studies as originally authorized. Similarly, repeat sleep testing requested at a different facility based solely on provider preference may not be approved for medical necessity.
- When multiple sleep tests are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior sleep tests were inconclusive, or why additional/follow-up studies are needed.
 - How the results will impact patient management or treatment decisions.

Indications

- **Initial heated and non-heated PAP humidifier set-up** is considered appropriate if **ALL** of the following are **TRUE**:
 - Device is requested by treating physician; **AND**
 - Positive airway pressure (PAP) device has been approved.

Non-Indications

- **Positive pressure ventilation (PPV)** is not considered appropriate if **ANY** of the following is **TRUE**¹⁶:
 - Airway obstruction secondary to a mass; **OR**
 - Anticipated need for prolonged mechanical ventilation; **OR**
 - Encephalopathy or altered mental status; **OR**
 - Facial trauma or facial defects; **OR**
 - Gastrointestinal bleeding; **OR**
 - Hemodynamic instability; **OR**
 - Need for intubation.

Service: Replacement Heated and Non-Heated PAP Humidifier

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing sleep medicine diagnostic testing, durable medical equipment (DME), and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior sleep testing, and details of previous treatments. Sleep medicine diagnostic testing, DME, and procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- Repeat sleep testing due to technical issues—such as signal artifact or loss of signal—may not be considered medically necessary, as it is the responsibility of the sleep testing center to deliver appropriate, high-quality studies as originally authorized. Similarly, repeat sleep testing requested at a different facility based solely on provider preference may not be approved for medical necessity.
- When multiple sleep tests are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior sleep tests were inconclusive, or why additional/follow-up studies are needed.
 - How the results will impact patient management or treatment decisions.

Indications

- **Replacement heated and non-heated PAP humidifier** is considered appropriate if **ANY** of the following is **TRUE**:
 - Greater than 6 months since last replacement; **OR**
 - Humidifier is not operating.

Non-Indications

- **Positive pressure ventilation (PPV)** is not considered appropriate if **ANY** of the following is **TRUE**¹⁶:
 - Airway obstruction secondary to a mass; **OR**
 - Anticipated need for prolonged mechanical ventilation; **OR**
 - Encephalopathy or altered mental status; **OR**
 - Facial trauma or facial defects; **OR**
 - Gastrointestinal bleeding; **OR**
 - Hemodynamic instability; **OR**
 - Need for intubation.

Medical Evidence

Patil et al. (2024) discussed a systematic review by the Agency for Healthcare Research and Quality (AHRQ) on long-term outcomes in obstructive sleep apnea (OSA). Patients who received CPAP therapy showed stronger, statistically significant associations between CPAP treatment for OSA and reduced all-cause mortality, which remained when analyses included randomized control trials (RCTs) and non-RCTs. The studies also addressed excessive daytime sleepiness (EDS), which can increase symptoms of OSA. Therapy with CPAP has short-term benefits, and symptoms return when treatment is discontinued. The American Academy of Sleep Medicine (AASM) conducted a systematic review and meta-analysis of 33 RCTs. Overall, there was a high level of evidence supporting CPAP therapy for patients with EDS; the AASM also strongly recommended CPAP therapy.¹⁷

Masa et al. (2020) conducted an RCT on obesity hypoventilation syndrome (OHS) and cardiac dysfunction. A total of 196 patients with OHS and severe OSA were included; a 3-year timeframe was used to determine the efficacy of noninvasive ventilation (NIV) and CPAP. Of the patients, 102 received CPAP therapy, and 94 received NIV (two levels of pressure). Both therapies showed similar improvement, specifically left ventricular diastolic dysfunction and reduced left atrial diameter. Respiratory function and dyspnea also improved, thus demonstrating the efficacy of both CPAP and NIV. (ClinicalTrials.gov Identifier: NCT01405976).¹⁸

The AHRQ investigated the use of noninvasive positive pressure ventilation (NIPPV) for adults with chronic respiratory failure due to chronic obstructive pulmonary disease (COPD), thoracic restrictive disorders (TRD), neuromuscular disease (NMD), and obesity hypoventilation syndrome (OHS). The systematic review included 68 studies with a total of 53,733 patients. For all conditions, NIPPV demonstrated a significant reduction in mortality (statistically and clinically). Patients with COPD demonstrated decreased hospitalizations, intubations, and dyspnea. Patients with TRD, NMD, OHS, and other lung diseases demonstrated increased exercise tolerance, quality of life, and sleep quality; dyspnea and hospitalizations decreased.¹⁹

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	02/13/2025	Original Date.
Version 2	05/01/2025	Added indication and codes (E0561, E0562) for heated and non-heated humidifiers: "Either a heated or non-heated humidifier is considered medically necessary for use with BiPAP or CPAP". Removed 2 bullets for "replacement of the current PAP device": Change in the structure of the patient's mouth; The appliance is worn due to excessive use and is unable to be repaired. Added indication for replacement of either a heated or non-heated humidifier for use with BiPAP or CPAP.
Version 3	05/07/2026	Annual Review. Updated indications for: CPAP or APAP; bilevel positive airway pressure for central sleep apnea, COPD, hypoventilation syndrome, continuation of CPAP or bilevel positive airway pressure, replacement CPAP or bilevel positive airway pressure, initial heated and non-heated PAP humidifier set-up, and replacement heated and non-heated PAP humidifier. Added 1 reference.



Cohere Medical Policy – Positive Pressure Ventilation

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: February 13, 2025

Important Notices

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Guideline Information:

Specialty Area: Sleep Medicine

Guideline Name: Cohere Medical Policy – Positive Pressure Ventilation

Date of last literature review: 2/9/2025

Document last updated: 2/10/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Positive Pressure Ventilation

Recommended Clinical Approach

Positive pressure ventilation (PPV) can be delivered via noninvasive positive pressure ventilation (NIPPV) using a tight-fitting mask that covers the patient's nose or both the nose and mouth. NIPPV is administered via continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP), or bilevel positive airway pressure (BiPAP). CPAP is used to treat obstructive sleep apnea (OSA); BiPAP is used for patients with OSA and obesity-hypoventilation syndrome (OHS).¹

Medical Necessity Criteria

Indications

→ **Positive pressure ventilation (PPV)** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ For continuous positive airway pressure (CPAP) or automatic positive airway pressure (APAP) with **ANY** of the following:
 - Obstructive sleep apnea (OSA)* and **ANY** of the following²:
 - Adults (age 18 or older) with **ANY** of the following³⁻⁴:
 - ◆ Apnea hypopnea index (AHI) or respiratory event index (REI) is **ANY** of the following⁵:
 - 5–14.9 events per hour (mild OSA) with a condition and/or symptoms (e.g., cardiovascular, metabolic, renal, pulmonary, neuropsychiatric)⁶; **OR**
 - 15–29.9 events per hour (moderate OSA)⁷; **OR**
 - Greater than or equal to 30 events per hour (severe OSA)⁷; **OR**
 - ◆ Preoperative preparation that is intended to improve or optimize the patient's perioperative physical status⁸; **OR**
 - Children (age 17 and under) with **ALL** of the following:
 - ◆ AHI or REI is **ANY** of the following⁹⁻¹⁰:

- 1-4 events per hour (mild OSA) with a condition and/or symptoms (e.g., cardiovascular, metabolic, renal, pulmonary, neuropsychiatric); **OR**
- 5-9 events per hour (moderate OSA); **OR**
- 10 or more events per hour (severe OSA); **AND**
- ◆ **ANY** of the following:
 - Persistent OSA and the patient does not qualify for site-specific upper airway treatment¹¹; **OR**
 - Persistent OSA with **ANY** of the following (including post-adenotonsillectomy)¹²:
 - Frequent snoring (3 times or more per week); **OR**
 - Labored breathing during sleep; **OR**
 - Gasps, snorting noises, or observed episodes of apnea; **OR**
 - Sleep enuresis (especially secondary enuresis) following at least 6 months of continence; **OR**
 - Sleeping in a seated position or with the neck hyperextended; **OR**
 - Cyanosis; **OR**
 - Headaches on awakening; **OR**
 - Daytime sleepiness; **OR**
 - Attention deficit hyperactivity disorder (ADHD); **OR**
 - Learning problems; **OR**
 - Underweight or overweight; **OR**
 - Tonsillar hypertrophy; **OR**
 - Adenoidal facies; **OR**
 - Micrognathia/retrognathia; **OR**
 - High-arched palate; **OR**
 - Failure to thrive; **OR**
 - Hypertension; **OR**
 - Upper airway resistance syndrome (UARS) with **ALL** of the following¹³:
 - A CPAP device is to be used nightly¹³; **AND**

- **ALL** of the following¹⁴:
 - ◆ AHI less than 5 events per hour; **AND**
 - ◆ A minimum SpO₂ of greater than or equal to 92%, the presence of airflow limitation during sleep for greater than or equal to 5% of total sleep time; **AND**
 - ◆ Daytime sleepiness and/or fatigue; **OR**
- ◆ For bilevel positive airway pressure (BiPAP) with **ANY** of the following:
 - Failure of CPAP with **ANY** of the following:
 - The device is uncomfortable; **OR**
 - The patient is intolerant; **OR**
 - The patient has a contraindication; **OR**
 - CPAP was ineffective; **OR**
 - **ANY** of the following:
 - Central sleep apnea (CSA) with **ALL** of the following¹⁵:
 - ◆ **ANY** of the following:
 - CSA is related to congestive heart failure (CHF); **OR**
 - Initial treatment with CPAP therapy is to normalize the apnea-hypopnea index (AHI); **AND**
 - ◆ An adaptive servo-ventilation (ASV) device is to be used nightly¹⁶; **AND**
 - Chronic obstructive pulmonary disease (COPD) for **ALL** of the following:
 - ◆ **ANY** of the following:
 - Prevention of acute respiratory acidosis (normal or elevated arterial CO₂ tension [PaCO₂] with normal pH)¹⁷; **OR**
 - Prevention of endotracheal intubation and invasive mechanical ventilation in a patient with mild to moderate acidosis and respiratory distress, with the aim of preventing deterioration to a point when invasive ventilation would be considered¹⁷; **OR**

- An alternative to invasive ventilation in a patient with severe acidosis and more severe respiratory distress¹⁷; **OR**
- The patient has sleep-associated hypoventilation (nocturnal hypoxemia);
AND
 - ◆ A BiPAP device is to be used nightly; **OR**
- Obesity hypoventilation syndrome (OHS) and **ALL** of the following:
 - ◆ **ANY** of the following:
 - For the initial treatment of a stable ambulatory adult patient with OHS¹⁸; **OR**
 - Concurrent severe OSA (AHI greater than or equal to 30 events per hour) presenting with chronic stable respiratory failure; **AND**
 - ◆ A BiPAP device is to be used nightly; **AND**
- Progressive neuromuscular disease with **ALL** of the following¹⁹:
 - ◆ **ANY** of the following:
 - Chronic respiratory failure; **OR**
 - Sleep-related breathing disorders; **AND**
 - ◆ A BiPAP device is to be used nightly or more often as needed as the disease progresses;
AND
- Thoracic cage abnormality with **ALL** of the following:
 - ◆ **ANY** of the following²⁰:
 - An arterial blood gas PaCO₂, done while awake and breathing the beneficiary's prescribed FIO₂ is greater than or equal to 45 mm Hg; **OR**
 - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing the beneficiary's prescribed recommended FIO₂; **OR**

- If the patient has neuromuscular disease, **ANY** of the following:
 - Maximal inspiratory pressure is less than 60 cm H₂O; **OR**
 - Forced vital capacity is less than 50% predicted; **OR**
 - COPD does not contribute significantly to the patient's pulmonary limitation; **AND**
- ◆ A BiPAP device is to be used nightly; **OR**
- ◆ For continued coverage of BiPAP or CPAP beyond the initial 90-day period, and **ALL** of the following are **TRUE**:
 - Documentation stating that a re-evaluation demonstrated improvement by the patient and continued use will likely provide additional improvement; **AND**
 - The patient is compliant and uses the device for at least 4 or more hours a night for at least 70% of 30 consecutive nights²¹; **AND**
 - **ANY** of the following^{**}:
 - The current device is useable and the patient does not require another device; **OR**
 - Replacement of the current device for **ANY** of the following:
 - Change in the structure of the patient's mouth; **OR**
 - The appliance is worn due to excessive use and unable to be repaired; **OR**
 - The appliance has reached a 5-year reasonable useful lifetime (RUL)²²; **OR**
 - Repairs, maintenance, or replacement are not covered under a manufacturer's warranty.

**** NOTE:** The patient's plan determines whether a device should be rented or purchased. General guidance is that when the rental cost exceeds the cost to purchase a device, consideration shall be given to purchase the device. The total covered cost cannot exceed the purchase or rental price.

Non-Indications

→ **Positive pressure ventilation (PPV)** is not considered appropriate if

ANY of the following is **TRUE**²³:

- ◆ The need for intubation; **OR**
- ◆ Encephalopathy or altered mental status; **OR**
- ◆ Hemodynamic instability; **OR**
- ◆ Facial trauma or facial defects; **OR**
- ◆ Airway obstruction secondary to a mass; **OR**
- ◆ Anticipated need for prolonged mechanical ventilation; **OR**
- ◆ Gastrointestinal bleeding.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0601	Continuous positive airway pressure (CPAP) device

Definitions

Apnea Hypopnea Index (AHI): number of apneas and hypopneas per total sleep time⁵

Respiratory Disturbance Index (RDI): number of apneas and hypopneas and respiratory effort-related arousals (RERAs) per total sleep time⁵

Respiratory Event Index (REI): number of apneas and hypopneas per monitoring time⁵

Medical Evidence

Patil et al. (2024) discuss a systematic review by the Agency for Healthcare Research and Quality (AHRQ) of long-term outcomes and obstructive sleep apnea (OSA). Patients who received CPAP therapy showed “stronger, statistically significant associations between CPAP treatment for OSA and reduced all-cause mortality, which remained when analyses included randomized control trials (RCTs) and non-RCTs. The studies also address excessive daytime sleepiness (EDS), which can increase symptoms of OSA. Therapy with CPAP has short-term benefits, and symptoms return when treatment is discontinued. The American Academy of Sleep Medicine (AASM) conducted a systematic review and meta-analysis of 33 RCTs. Overall, there is a high level of evidence for CPAP therapy for patients with EDS; the AASM also strongly recommends CPAP therapy.”²⁴

Masa et al. (2020) conducted an RCT on obesity hypoventilation syndrome (OHS) and cardiac dysfunction. The focus of the secondary analysis was the Pickwick Project, the largest multicenter RCT on OHS. A total of 196 patients with OHS and severe OSA were included; a 3-year timeframe was used to determine the efficacy of noninvasive ventilation (NIV) and CPAP. Of the patients, 102 received CPAP therapy, and 94 received NIV (two levels of pressure). Both therapies showed similar improvement, specifically left ventricular diastolic dysfunction and reduced left atrial diameter. Respiratory function and dyspnea also improved, thus demonstrating the efficacy of both CPAP and NIV. (ClinicalTrials.gov Identifier: NCT01405976).²⁵

Wang et al. (2019) investigated the use of noninvasive positive pressure ventilation (NIPPV) for adults with chronic respiratory failure due to chronic obstructive pulmonary disease (COPD), thoracic restrictive disorders (TRD), neuromuscular disease (NMD), and obesity hypoventilation syndrome (OHS). The systematic review included 68 studies with a total of 53,733 patients. For all conditions, NIPPV demonstrated a significant reduction in mortality (statistically and clinically). Patients with COPD demonstrated decreased hospitalizations, intubations, and dyspnea. Patients with TRD, NMD, OHS, and other lung diseases demonstrated increased exercise tolerance, quality of life, and sleep quality; dyspnea and hospitalizations decreased.²⁶

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Clinical Guideline Revision History/Information

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Cohere Medicare Advantage Policy – Sleep Study/Polysomnography (PSG)

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Sleep Medicine

Guideline Name: Cohere Medicare Advantage Policy - Sleep Study/Polysomnography (PSG)

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Sleep Study/Polysomnography (PSG)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻¹⁴

- [National Coverage Determination \(NCD\). Continuous positive airway pressure \(CPAP\) therapy for obstructive sleep apnea \(OSA\) \(240.4\)](#)
- [National Coverage Determination \(NCD\). Sleep testing for obstructive sleep apnea \(OSA\) \(240.4.1\)](#)
- [Local Coverage Determination \(LCD\). Polysomnography and other sleep testing \(L33405\)](#)
 - [Billing and Coding: Polysomnography and sleep testing \(A57496\)](#)
- [Local Coverage Determination \(LCD\). Outpatient sleep studies \(L35050\)](#)
 - [Billing and Coding: Outpatient sleep studies \(A56923\)](#)
- [Local Coverage Determination \(LCD\). Polysomnography \(L36593\)](#)
 - [Billing and Coding Article. Polysomnography \(A56995\)](#)
- [Local Coverage Determination \(LCD\). Polysomnography and other sleep studies \(L36839\)](#)
 - [Billing and Coding: Polysomnography and other sleep studies \(A56903\)](#)
- [Local Coverage Determination \(LCD\). Polysomnography and other sleep studies \(L36861\)](#)
 - [Billing and Coding: Polysomnography and other sleep studies \(A57697\)](#)
- [Local Coverage Determination \(LCD\). Polysomnography and other sleep studies \(L36902\)](#)
 - [Billing and Coding: Polysomnography and other sleep studies \(A57049\)](#)

Description

Sleep study/polysomnography (PSG) is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters during sleep (e.g., brain waves, blood oxygen level, heart rate, breathing rate, and eye and leg movements) for 6 hours or more, together with the review and interpretation of the records by a physician. Results are reviewed and interpreted by a physician. A comprehensive sleep evaluation must include a sleep history (e.g., snoring, apneas, daytime sleepiness), body mass index (BMI), neck circumference, cardiopulmonary examination, and identification of co-morbid sleep disorders and medical conditions.

Sleep study/PSG is performed to diagnose various sleep disorders. The gold standard for diagnosing obstructive sleep apnea (OSA) is overnight or split-night technologist-attended facility-based PSG. Split-night studies are performed to diagnose strongly suspected OSA and evaluate response to continuous positive airway pressure (CPAP) treatment over a one-night period¹. Completing the CPAP titration study on a second night may be appropriate. Two tests may be used in addition to PSG testing. Multiple sleep latency tests (MSLT) measure daytime sleepiness and aid in diagnosing types 1 and 2 narcolepsy and idiopathic hypersomnia. Maintenance of wakefulness tests (MWTs) measures the ability to stay awake.¹⁵

Sleep studies are performed in settings that include hospitals and outpatient sleep laboratories (accredited by the American Academy of Sleep Medicine, Accreditation Commission for Health Care, or The Joint Commission) as well as in the patient's home. Providers should hold certification or accreditation from any of the following organizations^{3,7,16}:

- Diplomate of the American Board of Sleep Medicine (ABSM)
- Sleep certification from the following:
 - American Board of Internal Medicine (ABIM)
 - American Board of Family Medicine (ABFM)
 - American Board of Pediatrics (ABP)
 - American Board of Psychiatry and Neurology (ABPN)
 - American Board of Otolaryngology (ABOto)
 - American Osteopathic Board of Neurology and Psychiatry (AOBNP)
 - American Osteopathic Board of Family Medicine, (AOBFP)
 - American Osteopathic Board of Internal Medicine, (AOBIM)

- American Osteopathic Board of Ophthalmology and Otorhinolaryngology (AOBOO)
- Physician staff member of a credentialed sleep center or laboratory that has active physician staff members meeting the physician credential criteria above.

Sleep technicians performing services should meet the requirements of the following organizations:

- American Board of Sleep Medicine (ABSM) (e.g., Registered Sleep Technologist [RST])
- Board of Registered Polysomnographic Technologists (BRPT) (e.g., Registered Polysomnographic Technologist [RPSGT])
- National Board for Respiratory Care (NBRC) (e.g., Certified Pulmonary Function Technologist [CPFT], Registered Pulmonary Function Technologist [RPFT], Certified Respiratory Therapist [CRT], Registered Respiratory Therapist [RRT]).

Medical Necessity Criteria

Indications

A **sleep study**^A is considered appropriate if **ANY** of the following is **TRUE**¹⁷:

- **Home-based, non-attended sleep study** with **ANY** of the following:
 - For an initial home study when the patient is an adult with clinical signs and symptoms of OSA^B; **OR**
 - Repeat home study and **ANY** of the following^{3,17-18}:
 - The first study was inconclusive due to technical or equipment failure; **OR**
 - The patient is unable to sleep or complete enough hours of sleep to allow a clinical diagnosis; **OR**
 - The results were inconclusive or ambiguous; **OR**
 - For re-evaluation due to weight change; **OR**
- **Facility-based, technologist-attended PSG (Type I)** with **ANY** of the following:
 - For an initial facility-based study when the patient is an adult with clinical signs and symptoms of OSA^B; **OR**
 - **ANY** of the following are suspected with planned multiple sleep latency testing (MSLT)¹⁵:
 - Narcolepsy with **ANY** of the following:
 - Cataplexy; **OR**

- Excessive daytime sleepiness; **OR**
- Hallucinations with the onset of sleep or awakening; **OR**
- Disrupted nighttime sleep; **OR**
- Sleep paralysis; **OR**
- Central disorders of hypersomnia with **ANY** of the following:
 - Sleep inertia; **OR**
 - Unrefreshed sleep with adequate or long sleep time; **OR**
- An in-laboratory sleep study is needed when a home sleep study cannot be performed with **ANY** of the following¹⁹:
 - Obesity hypoventilation syndrome (defined as a body mass index [BMI] greater than 30, daytime hypercapnia [partial pressure of carbon dioxide, PaCO₂, greater than 45 mm Hg without other causes such as kyphosis, myopathy, hypothyroidism, or lung disease]); **OR**
 - Awake daytime hypercapnia (partial pressure of carbon dioxide, PaCO₂, greater than or equal to 45 mm Hg without other causes such as kyphosis, myopathy, hypothyroidism, or lung disease – serum bicarbonate greater than 28 is considered an alternative in the absence of PaCO₂ from arterial blood gases); **OR**
- Suspected central sleep apnea (CSA); **OR**
- Evaluation of parasomnias (e.g., undesirable or unpleasant occurrences during sleep, sleepwalking, sleep terrors, rapid eye movement, sleep behavior disorder²⁰, history of repeated violent or injurious episodes during sleep) with **ANY** of the following³⁷:
 - The patient has a history of parasomniac episodes during sleep that result in harm to the patient or others; **OR**
 - To assist with the diagnosis of paroxysmal arousals or other sleep disruptions that are thought to be seizure-related when the initial clinical evaluation and results of a standard EEG are inconclusive; **OR**
 - To evaluate sleep-related behaviors that are violent or otherwise potentially injurious to the patient; **OR**
 - The patient has a sleep behavior suggestive of parasomnias that are unusual or atypical due to **ALL** of the following:
 - Age at onset; **AND**
 - Time, duration, or frequency of occurrence of the behavior; **AND**
 - Specifics of the particular motor patterns are in question (e.g., stereotypical, repetitive, or focal); **OR**

- In situations with forensic considerations (e.g., if onset follows trauma or if the events themselves have been associated with personal injury); **OR**
- When the presumed parasomnia or sleep-related epilepsy does not respond to conventional therapy; **OR**
- In cases of typical, uncomplicated, and non-injurious parasomnias when the diagnosis is not clearly delineated; **OR**
- The pediatric patient has suspected sleep apnea with an initial PSG test indicated by **ANY** of the following^{16,21-22}:
 - Evaluation for obstructive sleep apnea (OSA) pre- or post-removal of enlarged tonsils or adenoids; **OR**
 - Down syndrome; **OR**
 - Chiari malformation; **OR**
 - Craniofacial malformation; **OR**
 - Neuromuscular disorder; **OR**
 - Skeletal dysplasia (e.g., achondroplasia); **OR**
 - Suspected periodic limb movement disorder²³; **OR**
 - Signs and symptoms of OSA with **ANY** of the following:
 - Snoring; **OR**
 - Daytime sleepiness; **OR**
 - Mouth breathing; **OR**
 - Nocturnal apnea; **OR**
 - Enuresis; **OR**
 - Pulmonary hypertension; **OR**
 - Nasal flaring or other signs of breathing difficulty; **OR**
 - Failure to thrive (weight less than 5th percentile for age); **OR**
 - Hyponasal speech; **OR**
 - Behavioral problems (e.g., hyperactivity, developmental delay, difficulties in school); **OR**
- An attended, full-night titration study including **ALL** of the following:
 - Unattended auto-titration with APAP or auto bi-level PAP is contraindicated; **AND**
 - OSA with **ANY** of the following:
 - Apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) greater than or equal to 15 events per hour; **OR**
 - AHI, RDI, or REI greater than or equal to 5-14 events per hour with **ANY** of the following:

- Excessive daytime sleepiness; **OR**
- Insomnia; **OR**
- Mood disorders (e.g., anxiety, depression); **OR**
- Impaired cognition; **OR**
- History of stroke; **OR**
- Hypertension; **OR**
- Ischemic heart disease; **AND**
- **ANY** of the following:
 - The patient has **ANY** of the following co-morbid conditions:
 - Heart failure with New York Heart Association (NYHA) Classification III or IV or reduced ejection fraction less than or equal to 40%; **OR**
 - Cardiac arrhythmia(s) (acute, uncontrolled, or refractory) with documented symptoms; **OR**
 - Severe asthma with daily use of oral corticosteroids and/or immunomodulator biologics; **OR**
 - Pulmonary disease (e.g., moderate to severe COPD or interstitial lung disease) as diagnosed on pulmonary function studies (PFTs) and the patient requires chronic oxygen use; **OR**
 - Obesity hypoventilation syndrome (OHS); **OR**
 - Moderate to severe pulmonary hypertension; **OR**
 - Neuromuscular/neurodegenerative disorders with restrictive disease or hypoventilation (e.g., amyotrophic lateral sclerosis [ALS], post-polio syndrome, myasthenia gravis, Guillian-Barré syndrome, polymyositis, kyphoscoliosis); **OR**
 - Chronic opioid medication use; **OR**
 - The patient has a second or associated sleep disorder other than OSA, including **ANY** of the following:
 - Central nervous system disorders that increase the risk of CSA (e.g., Arnold Chiari malformation); **OR**
 - CSA or treatment-emergent sleep apnea; **OR**
 - Acute nocturnal seizures; **OR**
 - Narcolepsy or related symptoms following the evaluation and treatment of OSA in accordance with the patient's documented adherence to therapy; **OR**
 - Complex parasomnias that may include injurious, disruptive, or violent behavior (e.g., sleepwalking, REM behavior disorder); **OR**

- Periodic limb movement disorder (PLMD); **OR**
- The patient failed a recent home APAP trial due to **ANY** of the following:
 - Auto bi-level therapy is contraindicated or was ineffective; **OR**
 - PAP therapy was not tolerated after a trial of at least 1 month with no previous attended titration; **OR**
 - Adequate objective adherence to therapy (greater than or equal to 4 hours per night for at least 70% of nights in a 30-day consecutive period as documented by APAP download) with **ANY** of the following:
 - Symptoms of residual excessive daytime sleepiness; **OR**
 - Residual AHI greater than or equal to 5 as evidenced by APAP download; **OR**
- Split-night protocol for strong pre-test suspicion of OSA with the initiation of treatment with a positive pressure device, including **ANY** of the following^{2,13,17}:
 - For initial testing when the patient is an adult with clinical signs and symptoms of OSA (e.g., snoring loudly, daytime sleepiness, observed sleep apnea [gasping, choking, or breathing that has stopped]); **OR**
 - For repeat split-night testing with **ANY** of the following:
 - The patient has **ANY** of the following:
 - Symptoms of OSA that persist or recur despite PAP therapy; **OR**
 - A change in weight (gain or loss greater than or equal to 10% of total body weight) when OSA symptoms have worsened or improved and re-evaluation is required to determine needed therapy modifications; **OR**
 - A change in cardiovascular status (e.g., stroke, arrhythmia, uncontrolled hypertension, hospitalization for heart failure); **OR**
 - To re-evaluate the indicators of OSA after **ANY** of the following:
 - Adenoidectomy; **OR**
 - Tonsillectomy; **OR**
 - Maxillomandibular advancement surgery (MMA); **OR**
 - Uvulopalatoplasty (UPPP); **OR**
 - Other surgery related to the upper airway; **OR**
 - A non-diagnostic home sleep apnea test (HSAT) performed no more than one year prior with **ANY** of the following:
 - An OSA diagnosis was not determined when there was a high pretest probability of OSA; **OR**

- An effort was made to perform the test again if the original test was determined to be technically inadequate; **OR**
 - The patient requires evaluation to begin using a fabricated oral mandibular advancement appliance (OAT); **OR**
- Repeat PSG test, as indicated by **ANY** of the following:
 - Confirmation of the efficacy of prescribed therapy is needed (e.g., oral appliance, postoperative assessment of response to intervention)¹³; **OR**
 - To ascertain whether CPAP is still needed at the previously titrated pressure if the patient experiences substantial weight gain or weight loss on CPAP for the treatment of sleep-related breathing disorders¹³; **OR**
 - The patient shows insufficient clinical response or symptoms return despite a good initial response to CPAP¹³; **OR**
 - Assessing treatment response after upper airway surgical procedures, or initial treatment with oral appliances for **ANY** of the following^{13,24-25}:
 - Initial treatment with oral appliances (pre-implantation or re-evaluation of known OSA) with **ANY** of the following:
 - PAP failure or PAP intolerance with BMI less than or equal to 35 with no recent sleep study; **OR**
 - A significant change in weight and/or symptoms; **OR**
 - After upper airway surgical procedures (post-implantation) with **ANY** of the following:
 - Initial PSG titration; **OR**
 - PSG titration previously performed with insufficient clinical response, weight gain and/or return of symptoms; **OR**
- Multiple sleep latency test (MSLT) performed in a sleep laboratory for **ANY** of the following¹⁵:
 - For initial MSLT with **ALL** of the following:
 - Evaluation of presence or treatment response for features of **ANY** of the following:
 - Central disorders of hypersomnia; **OR**
 - Narcolepsy (including, cataplexy, EDS, sleep paralysis, hypersomnia); **AND**
 - Testing consists of 5 episodes of 20-minute nap trials at 2-hour intervals, measuring the onset of sleep and rapid eye movement

(REM) sleep, immediately following a negative PSG when narcolepsy is suspected; **OR**

- Repeat MSLT may be required if initial results are indeterminate or negative when narcolepsy is suspected; **OR**
- Maintenance of wakefulness tests (MWT) performed in a sleep laboratory are considered appropriate with **ANY** of the following:
 - For initial MWT with **ALL** of the following²⁶:
 - To assess an individual's ability to remain awake when his or her inability to remain awake constitutes a public or personal safety issue; **AND**
 - To assess response to treatment and the patient has excessive daytime sleepiness; **OR**
 - Repeat MWT may be required if initial results are indeterminate or negative when symptoms persist.

Non-Indications

A sleep study/polysomnogram is not considered appropriate if **ANY** of the following is **TRUE**:

- Attended full-channel polysomnography or home sleep testing for evaluating **ANY** of the following conditions:
 - Circadian rhythm disorders; **OR**
 - Depression; **OR**
 - Insomnia; **OR**
- Actigraphy for any sleep disorder; **OR**
- Daytime sleep studies for **ANY** of the following:
 - MWT is unproven and not medically necessary in children and adolescents less than 18 years of age; **OR**
 - Abbreviated daytime sleep studies (e.g., PAP-Nap) are not medically necessary due to insufficient evidence of efficacy.

Definitions

^A**The sleep study/polysomnography** includes the following^{3,7,13,16}:

- A 1-4 lead electroencephalogram (EEG) to measure global neural encephalographic activity using electrodes placed on the scalp
- Electrooculogram (EOG) to measure eye movements using electrodes placed near the outer canthus of each eye
- A submental electromyogram (EMG) to measure submental electromyographic activity using electrodes placed over the mentalis, submental muscle, and/or masseter regions
- Rhythm electrocardiogram (ECG) with 2 or 3 chest leads
- Nasal and/or oral airflow
- Ventilation and respiratory effort by chest-wall and abdominal movement are measured using strain gauges, piezoelectric belts, inductive plethysmography, impedance or inductance pneumography, endo esophageal pressure, or by intercostal EMG
- Gas exchange (oxygen saturation [SpO₂]) by oximetry, transcutaneous monitoring, or end-tidal gas analysis
- Extremity muscle activity, motor activity-movement using EMG
- Body positions via mercury switches or by direct observation
- Recordings of vibration (frequency and/or volume) may be recorded
- Transcutaneous CO₂, esophageal pH, penile tumescence, and bipolar EEG
- For polysomnogram, sleep is recorded and staged

^B**Obstructive sleep apnea signs and symptoms demonstrated by either of the following:**

1. Excessive daytime sleepiness (e.g., falling asleep while driving) and two or more of the following symptoms/conditions:
 - Snoring loudly (e.g., enough to be heard through a closed door, waking others)
 - Observed sleep apnea, gasping, choking, or breathing that has stopped
 - Diagnosed hypertension
 - Body mass index (BMI) greater than or equal to 35 kg/m²
 - Age 50 years or older
 - Large neck circumference (greater than 17 inches in men; greater than 16 inches in women)¹⁷

2. A validated questionnaire (e.g., STOP BANG or Berlin) indicating at least low risk for OSA may be utilized instead of the above signs and symptoms.[27-28](#)

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95806	Sleep study, unattended, simultaneous recording of,

	heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of sleep study or polysomnography. This process helps prevent incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Generally, no major risks or clinical harms are associated with sleep study/polysomnography, which is non-invasive and painless.
- The most common side effect is skin irritation caused by the adhesive used to attach test sensors to the skin.
- Some patients may find it uncomfortable or difficult to sleep in the laboratory setting with sensors attached to the skin.
- Some patients (e.g., trauma survivors, or those hypersensitive to sound) may experience anxiety due to the unfamiliar settings of the sleep lab and the noise from the recording medical instruments.
- Although most sleep studies are performed at night, night-shift workers who generally sleep during the daytime might find it difficult to sleep at night. This problem can be circumvented by adjusting the time of the procedure based on individualized sleep schedules.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- A comprehensive sleep study may help diagnose various sleep disorders (e.g., sleep-related breathing disorders, periodic limb movement disorders, narcolepsy, sleepwalking, insomnia, etc.), including potentially life-threatening conditions such as obstructive sleep apnea (OSA), or adjust treatment plans for known sleep disorders. [29-30](#)
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive

medically necessary care. The criteria aim to balance the need for effective treatment with minimizing potential harms, providing numerous clinical benefits, and helping avoid unnecessary complications from inappropriate care. In addition, using these criteria is likely to create a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Evidence

Queisi et al. (2024) performed a retrospective review to compare polysomnographic (PSG) sleep parameters for people with multiple sclerosis (PwMS). The study evaluates a large single cohort from a single center versus existing published standards. A total of 299 PwMS were evaluated at a facility for polysomnography (PSG). Data included total sleep time (TST), sleep efficiency (SE), sleep onset latency (SOL), relative REM latency, total apnea-hypopnea indices (AHI), spontaneous arousal indices (AI), total periodic leg movements indices (PLMI), and sleep architecture metrics (e.g., the percentage spent in stages N1/N2, N3, and REM). Compared to normative data, PwMS had an average of 85.9 minutes shorter TST, 27.3 minutes longer SOL, 62.1 minutes longer REM latency, 10.7% lower SE, 16.4% more N1/N2, and 11.4% less N3. The population demonstrated a high prevalence of obstructive sleep apnea (OSA; 60.7%); the mean AHI was also higher by 11.1 events per hour. Fatigue is a primary symptom among PwMS. The study highlighted the need for established parameters for PwMS.³¹

The American Heart Association (AHA) (2021) issued a scientific statement regarding obstructive sleep apnea (OSA) and cardiovascular disease. Testing is recommended for cardiovascular conditions, including resistant hypertension, pulmonary hypertension, recurrent atrial fibrillation, heart failure, stroke, and for survivors of sudden cardiac death. Follow-up testing is recommended to determine the effectiveness of treatment.²⁹

The American Academy of Sleep Medicine (AASM) has published a guideline and position statements related to testing for OSA and other sleep disorders, including the following:

- Das et al. (2022) developed a position statement for AASM focusing on enhancing public health and safety by diagnosing and treating OSA in those in the transportation industry. Recommendations have included mandatory testing and treatment for OSA for rail and highway personnel in safety-sensitive positions.³²
- Kapur et al. (2017) published the *Clinical Practice Guideline for Diagnostic Testing for Adult Sleep Apnea*, with clinical recommendations using the Grading of Recommendations Assessment, Development, and Evaluation

(GRADE) system. A strong recommendation was made for facility-based testing rather than home testing for patients with significant cardiorespiratory disease, neuromuscular conditions with respiratory muscle weakness, a history of stroke, severe insomnia, or chronic opioid use.¹⁷

- Kirk et al. (2017) published a position statement regarding home sleep apnea testing for diagnosing OSA in children. The authors concluded that home testing is not recommended in children less than 18 years of age. Limited evidence exists comparing attended PSG to home testing.¹⁶

Khan et al. (2015) systematically reviewed the peer-reviewed literature regarding central disorders of hypersomnolence. They state that there have been significant advances in recent years, particularly in the diagnosis and management of narcolepsy type 1. A 24-hour PSG is important in the diagnosis of central disorders of hypersomnia.³⁰

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Policy Revision History/Information

Original Date: February 6, 2025		
Review History		
Version 2	03/13/2025	- Added criteria from CMS LCD L36593 for sleep study/PSG. - Updated the home-based, non-attended sleep study indication with STOP-BANG criteria. An indication was also added - "test is required within 24 months of the first consultation for hypoglossal nerve stimulation (HGNS) implant" (Corral et al, 2017 and Masa et al, 2011). - For the suspicion indications and use of Multiple Sleep Latency Testing (MSLT), added "central disorders of hypersomnia with ANY of the following: - Sleep inertia; OR - Unrefreshed sleep with adequate or long sleep time; OR" - Separated the indications for MSLT performed in a sleep laboratory and Maintenance of wakefulness tests (MWT). - Added indication for full-night titration study. - Rewrote the indication for the split-night protocol for strong pre-test suspicion of OSA. - Per CMS, included requirements for place of service and accreditation of the provider.

Version 3	04/17/2025	Boolean logic updates made: • On p. 6, previously, the first diamond bullet was “ANY of the following” – deleted and moved the bullets over one level to the left. • On p. 7 – bullet for “Transcutaneous CO2, esophageal pH, penile tumescence, and bipolar EEG” (<i>changed from an AND to an OR</i>) • On p. 7 – the main bullet for “home-based testing” was changed from an ANY to an ALL • On p. 8, under the bullet for “The patient is an adult with a high pretest probability of moderate to severe obstructive sleep apnea (OSA) with ALL of the following” – indented 2 bullets (“sleep study is recorded” and “sleep study is staged”) to the right to fix logic. • On p. 15, the indication for “split-night protocol” was updated from ALL to ANY (previously, the patient was required to meet both the initial and repeat criteria together). • On p. 20, changed the OR to AND – see the indication for “Maintenance of Wakefulness Tests (MWT)”, under the first sub-bullet for initial MWT (“to assess an individual’s ability to remain awake when his or her inability to remain awake constitutes a public or personal safety issue”).
Version 3.1	04/21/2025	Updated policy per CMS revisions for 03/20/2025 Updated Effective Date Updated Links and Bookmarks

Version 4	10/23/2025	Removed L34040 and A57698 links and references from policy- CMS retired 09/11/2025 Added L33405, A57496, L35050, A56923, L36839, A56903, L36861, A56797 to reflect CMS guidelines. Removed specific OSA symptom requirements. Home sleep testing indications refined to align more closely with CMS criteria.



Cohere Medical Policy – Sleep Study/Polysomnography (PSG)

Clinical Guidelines for Medical Necessity Review

Version: 2
Revision Date: February 6, 2025

Important Notices

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Medical Necessity Criteria

Service: Sleep Study/Polysomnography (PSG)

Recommended Clinical Approach

Sleep study/polysomnography (PSG) is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters during sleep (e.g., brain waves, blood oxygen level, heart rate, breathing rate, and eye and leg movements) for 6 hours or more. Results are reviewed and interpreted by a physician. A comprehensive sleep evaluation must include a sleep history (e.g., snoring, apneas, daytime sleepiness), body mass index (BMI), neck circumference, cardiopulmonary examination, and identification of co-morbid sleep disorders and medical conditions.

Sleep study/PSG is performed to diagnose various sleep disorders. The gold standard for diagnosing obstructive sleep apnea (OSA) is overnight or split-night, technologist-attended facility-based polysomnography (PSG). Split-night studies are performed both to diagnose strongly suspected OSA and to evaluate response to continuous positive airway pressure (CPAP) treatment over a one-night period.¹ Completing the CPAP titration study on a second night may be appropriate. Selected patients without severe comorbid conditions may be appropriate candidates for a portable or home sleep study. Two tests may be used in addition to PSG testing. Multiple Sleep Latency Tests (MSLT) measure daytime sleepiness and aid in diagnosing types 1 and 2 narcolepsy and idiopathic hypersomnia. Maintenance of Wakefulness Tests (MWTs) measures the ability to stay awake.²

Medical Necessity Criteria

Indications

- A **sleep study** is considered appropriate if **ANY** of the following is **TRUE**:
 - ◆ Home-based, non-attended sleep study and **ALL** of the following are **TRUE**:
 - For an initial home study when the patient is an adult with suspected sleep apnea, including excessive daytime sleepiness and **AT LEAST TWO** of the following^{1,3-5}:

- Snoring loudly (e.g., enough to be heard through a closed door, waking others); **OR**
- Daytime sleepiness (e.g., falling asleep while driving); **OR**
- Observed sleep apnea, gasping, choking, or breathing that has stopped; **OR**
- Diagnosed hypertension; **OR**
- Body mass index (BMI) greater than or equal to 35 kg/m²; **OR**
- Age 50 years or older; **OR**
- Large neck circumference (greater than 17 inches in men; greater than 16 inches in women); **OR**
- Repeat home study for **ANY** of the following^{1,3}:
 - The first study was inconclusive due to technical or equipment failure; **OR**
 - The patient is unable to sleep or complete enough hours of sleep to allow a clinical diagnosis; **OR**
 - The results were inconclusive or ambiguous; **OR**
 - For re-evaluation due to weight change; **OR**
- ◆ Facility-based, technologist-attended polysomnography (PSG) with **ANY** of the following:
 - Adult with suspected sleep apnea and **ALL** of the following:
 - Home sleep study is contraindicated; **AND**
 - For an initial facility-based study when the patient is an adult with suspected sleep apnea, including excessive daytime sleepiness and **AT LEAST TWO** of the following^{1,3-4}:
 - ◆ Snoring loudly (e.g., enough to be heard through a closed door, waking others); **OR**
 - ◆ Daytime sleepiness (e.g., falling asleep while driving); **OR**
 - ◆ Observed sleep apnea, gasping, choking, or breathing that has stopped; **OR**
 - ◆ Diagnosed hypertension; **OR**
 - ◆ Body mass index (BMI) greater than or equal to 35 kg/m²; **OR**
 - ◆ Age 50 years or older; **OR**

- ◆ Large neck circumference (greater than 17 inches in men; greater than 16 inches in women); **AND**
- **ANY** of the following¹:
 - ◆ Significant cardiopulmonary disease (forced expiratory volume in one second [FEV₁] % predicted of less than 70 or heart failure with left ventricular ejection fraction (LVEF) less than 45%)⁶⁻⁸; **OR**
 - ◆ Potential respiratory muscle weakness due to neuromuscular conditions; **OR**
 - ◆ History of stroke; **OR**
 - ◆ Chronic opiate medication use³; **OR**
 - ◆ Concern for a significant non-respiratory sleep disorder(s) that require evaluation (e.g., disorders of central hypersomnolence⁹, sleep-related movement disorders) or that interfere with the accuracy of home sleep apnea test (HSAT) (e.g., severe insomnia); **OR**
 - ◆ Environmental or personal factors that preclude the adequate acquisition and interpretation of data from HSAT; **OR**
 - ◆ The patient or caregiver is unable to safely use the equipment for home sleep study due to dexterity, mobility, or cognitive function; **OR**
 - ◆ A home sleep study was negative, inconclusive, or technically inadequate^{1,10}; **OR**
- Suspected narcolepsy with **ALL** of the following:
 - **ANY** of the following:
 - ◆ Cataplexy; **OR**
 - ◆ Excessive daytime sleepiness; **OR**
 - ◆ Hallucinations with the onset of sleep or awakening; **OR**
 - ◆ Sleep paralysis; **AND**
 - Multiple Sleep Latency Testing (MSLT) planned²; **OR**
- An in-lab sleep study is needed when a home sleep study cannot be performed, and **ANY** of the following is **TRUE**¹¹:
 - Obesity hypoventilation syndrome (defined as a body mass index [BMI] greater than 30, daytime

hypercapnia [partial pressure of carbon dioxide, PaCO₂, greater than 45 mm Hg without other causes such as kyphosis, myopathy, hypothyroidism, or lung disease]); **OR**

- Awake daytime hypercapnia (partial pressure of carbon dioxide, PaCO₂, greater than or equal to 45 mm Hg without other causes such as kyphosis, myopathy, hypothyroidism, or lung disease – serum bicarbonate greater than 28 is considered an alternative in the absence of PaCO₂ from arterial blood gases); **OR**
- Suspected central sleep apnea (CSA); **OR**
- Evaluation of parasomnias (e.g., undesirable or unpleasant occurrences during sleep, sleepwalking, sleep terrors, rapid eye movement, sleep behavior disorder¹², history of repeated violent or potentially injurious episodes during sleep) and **ALL** of the following is **TRUE**:
 - The patient has a history of parasomniac episodes during sleep that results in harm to the patient or others; **OR**
 - To assist with the diagnosis of paroxysmal arousals or other sleep disruptions that are thought to be seizure-related when the initial clinical evaluation and results of a standard EEG are inconclusive; **OR**
 - To evaluate sleep-related behaviors that are violent or otherwise potentially injurious to the patient; **OR**
 - The patient has a sleep behavior suggestive of parasomnias that are unusual or atypical due to **ALL** of the following:
 - ◆ Age at onset; **OR**
 - ◆ Time, duration, or frequency of occurrence of the behavior; **OR**
 - ◆ Specifics of the particular motor patterns are in question (e.g., stereotypical, repetitive, or focal); **OR**
 - In situations with forensic considerations (e.g., if onset follows trauma or if the events themselves have been associated with personal injury); **OR**

- When the presumed parasomnia or sleep-related epilepsy does not respond to conventional therapy; **OR**
- In cases of typical, uncomplicated, and non-injurious parasomnias when the diagnosis is not clearly delineated; **OR**
- The pediatric patient has suspected sleep apnea, and an initial PSG test is indicated by **ANY** of the following¹³⁻¹⁶:
 - Evaluation for obstructive sleep apnea (OSA) pre- or post-removal of enlarged tonsils or adenoids; **OR**
 - Down syndrome; **OR**
 - Chiari malformation; **OR**
 - Craniofacial malformation; **OR**
 - Neuromuscular disorder (e.g., Parkinson's disease, stroke with persistent neurological sequelae, Duchenne muscular dystrophy, multiple sclerosis with associated pulmonary disease, amyotrophic lateral sclerosis, myotonic dystrophy); **OR**
 - Skeletal dysplasia (e.g., achondroplasia); **OR**
 - Suspected periodic limb movement disorder¹⁵; **OR**
 - Signs and symptoms of OSA with **ANY** of the following:
 - ◆ Snoring; **OR**
 - ◆ Daytime sleepiness; **OR**
 - ◆ Mouth breathing; **OR**
 - ◆ Nocturnal apnea; **OR**
 - ◆ Enuresis; **OR**
 - ◆ Pulmonary hypertension; **OR**
 - ◆ Nasal flaring or other signs of breathing difficulty; **OR**
 - ◆ Failure to thrive (weight less than fifth percentile for age); **OR**
 - ◆ Hyponasal speech; **OR**
 - ◆ Behavioral problems (e.g., hyperactivity, developmental delay, difficulties in school); **OR**
- Split-night protocol for strong pretest suspicion of OSA and initiation of treatment with positive pressure device including **ALL** of the following¹:

- Apnea-hypopnea index (AHI) greater than 15 or 30 abnormal respiratory events **OR** greater than 5 with stipulated co-morbidities; **AND**
- CPAP titration is performed for a minimum of 3 hours; **OR**
- CPAP eliminated or nearly eliminated the abnormal respiratory events; **OR**
- Repeat PSG test, as indicated by **ANY** of the following:
 - For initiation of therapy; **OR**
 - Confirmation of the efficacy of prescribed therapy is needed (e.g., oral appliance, postoperative assessment of response to intervention); **OR**
 - Previous results were inconclusive or ambiguous;
 - Assessing treatment response for **ANY** of the following¹⁷⁻¹⁸:
 - ◆ Initial treatment with oral appliances (pre-implantation or re-evaluation of known OSA) with **ANY** of the following:
 - PAP failure or PAP intolerance with a BMI less than or equal to 35 and no recent sleep study; **OR**
 - A significant change in weight and/or symptoms; **OR**
 - ◆ After upper airway surgical procedures (post-implantation) with **ANY** of the following:
 - Initial PSG titration; **OR**
 - PSG titration previously performed with insufficient clinical response, weight gain and/or return of symptoms; **OR**
- ◆ Maintenance of Wakefulness Tests (MWT) or Multiple Sleep Latency Testing (MSLT) performed in a sleep laboratory are considered appropriate when **ANY** of the following is **TRUE**²:
 - For initial MSLT or MWT with **ALL** of the following:
 - Evaluation of presence or treatment response for features of narcolepsy (including, cataplexy, EDS, sleep paralysis, hypersomnia); **AND**
 - Testing consists of five 20-minute nap trials at 2-hour intervals, measuring the onset of sleep and rapid eye

- movement sleep, immediately following a negative PSG when narcolepsy is suspected; **OR**
- Repeat MSLT or MWT testing when initial results are indeterminate or negative with suspected narcolepsy.

Non-Indications

→ A **sleep study** is not considered appropriate if **ANY** of the following is **TRUE**^{1,3}:

- ◆ The patient is an adult and testing is for **ANY** of the following:
 - Home sleep study for **ANY** of the following:
 - The patient has **ANY** of the following:
 - ◆ Significant cardiopulmonary disease (forced expiratory volume in one second [FEV₁] % predicted of less than 70 or heart failure with left ventricular ejection fraction (LVEF) less than 45%)⁶⁻⁸; **OR**
 - ◆ Potential respiratory muscle weakness due to neuromuscular conditions¹⁹; **OR**
 - ◆ Restless legs syndrome¹⁹; **OR**
 - ◆ Hypoventilation syndrome (awake hypoventilation or suspected sleep-related hypoventilation); **OR**
 - ◆ Acute opioid use (medication not normally taken by the patient)²⁰; **OR**
 - ◆ Chronic opioid medication use²⁰; **OR**
 - ◆ History of stroke²¹; **OR**
 - ◆ Suspected sleep disorder other than OSA (e.g., insomnia, CSA, parasomnia, narcolepsy, severe insomnia)^{19,21}; **OR**
 - For the diagnosis of **ANY** of the following:
 - ◆ Circadian rhythm sleep disorders; **OR**
 - ◆ Chronic lung disease; **OR**
 - ◆ Preoperative evaluation for laser-assisted uvulopalatopharyngoplasty without clinical evidence of suspicion of OSA; **OR**
 - **ANY** of the following:
 - ◆ Actigraphy used for the diagnosis of sleep disorders; **OR**

- ◆ The patient or caregiver is unable to manage equipment; **OR**
- ◆ The patient is asymptomatic and testing is for general screening; **OR**
- Facility-based PSG and the patient has **ANY** of the following:
 - Actigraphy used for the diagnosis of sleep disorders; **OR**
 - Acute opioid use (medication not normally taken by the patient)²⁰; **OR**
 - A home sleep study was negative, inconclusive, or technically inadequate (e.g., missing data, equipment or sensor failure, the patient has congestive heart failure or COPD, the patient did not sleep enough) and a repeat home sleep study may be more appropriate^{1,10}; **OR**
 - For the diagnosis of **ANY** of the following:
 - ◆ Circadian rhythm sleep disorders; **OR**
 - ◆ Chronic lung disease; **OR**
 - ◆ Preoperative evaluation for laser-assisted uvulopalatopharyngoplasty without clinical evidence of suspicion of OSA; **OR**
- ◆ The request is for a pediatric home-based sleep study.¹⁶

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist

95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist

Medical Evidence

Queisi et al. (2024) performed a retrospective review to compare polysomnographic (PSG) sleep parameters for people with multiple sclerosis (PwMS). The study is a large single cohort from a single center versus existing published standards. A total of 299 PwMS were evaluated at a facility for polysomnography (PSG). Data included “total sleep time (TST), sleep efficiency (SE), sleep onset latency (SOL), Relative REM latency, total apnea-hypopnea indices (AHI), spontaneous arousal indices (AI), total periodic leg movements indices (PLMI) and, sleep architecture metrics” (e.g., the percentage spent in stages N1/N2, N3, and REM). Compared to normative data, PwMS had an average of 85.9 min shorter TST, 27.3 min longer SOL, 62.1 min longer REM latency, 10.7% lower SE, 16.4% more N1/N2, and 11.4% less N3. The population demonstrated a high prevalence of OSA (60.7%); the mean AHI was also higher by 11.1 events per hour. Fatigue is a primary symptom among PwMS – the study highlighted the need for established parameters for PwMS.²²

The American Heart Association (AHA) (2021) issued a scientific statement regarding obstructive sleep apnea (OSA) and cardiovascular disease. Testing is recommended for cardiovascular conditions, including resistant hypertension, pulmonary hypertension, recurrent atrial fibrillation, heart failure, stroke, and for survivors of sudden cardiac death. Follow-up testing is recommended to determine the effectiveness of treatment.⁶

The American Academy of Sleep Medicine (AASM) has published a guideline and position statements related to testing for OSA and other sleep disorders, including the following:

- Das et al. (2022) developed a position statement for AASM focusing on enhancing public health and safety by diagnosing and treating OSA in those in the transportation industry. Recommendations have included mandatory testing and treatment for OSA for rail and highway personnel in safety-sensitive positions.²³
- Kapur et al. (2017) published the *Clinical Practice Guideline for Diagnostic Testing for Adult Sleep Apnea*, with clinical recommendations using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system. A strong recommendation was made for facility-based testing rather than

home testing for patients with significant cardiorespiratory disease, neuromuscular conditions with respiratory muscle weakness, a history of stroke, severe insomnia, or chronic opioid use.¹

- Kirk et al. (2017) published a position statement regarding home sleep apnea testing for diagnosing OSA in children. The authors concluded that home testing is not recommended in children less than 18 years of age. Limited evidence exists comparing attended PSG to home testing.¹⁶

Khan et al. (2015) systematically reviewed the peer-reviewed literature regarding central disorders of hypersomnolence. They state that there have been significant advances in recent years, particularly in the diagnosis and management of narcolepsy type 1. A 24-hour PSG is important in the study of idiopathic hypersomnias.⁹

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Version 2	2/6/2025	• Annual review. • Reorganization of the boolean logic and indication order throughout the medical necessity criteria. • Literature review – Medical Evidence section updated.



Cohere Medicare Advantage Policy – Capsule Endoscopy

Clinical Policy for Medical Necessity Review

Version: 2.1

Policy Number: CHP-278-2.1

Cohere Health UMC Approval Date: December 11, 2025

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Next Annual Review: December 11, 2026

Important Notices

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Policy Information:

Specialty Area: Gastroenterology

Policy Name: Cohere Medicare Advantage Policy - Capsule Endoscopy

Policy Number: CHP-278-2.1

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Capsule Endoscopy

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻²³

- [Local Coverage Determination \(LCD\). Wireless capsule endoscopy \(L33774\)](#)
 - [Billing and Coding. Wireless capsule endoscopy \(A56704\)](#)
- [Local Coverage Determination \(LCD\). Endoscopy by capsule \(L34081\)](#)
 - [Billing and Coding. Endoscopy by capsule \(A56461\)](#)
- [Local Coverage Determination \(LCD\). Wireless capsule endoscopy \(L35089\)](#)
 - [Billing and Coding. Wireless capsule endoscopy \(A57753\)](#)
- [Local Coverage Determination \(LCD\). Wireless capsule endoscopy \(L36427\)](#)
 - [Billing and Coding. Wireless capsule endoscopy \(A56727\)](#)
- [Local Coverage Determination \(LCD\). Colon capsule endoscopy \(CCE\) \(L38571\)](#)
 - [Billing and Coding. Colon capsule endoscopy \(CCE\) \(A58294\)](#)
- [Local Coverage Determination \(LCD\). Colon capsule endoscopy \(CCE\) \(L38755\)](#)
 - [Billing and Coding. Colon capsule endoscopy \(CCE\) \(A58321\)](#)
- [Local Coverage Determination \(LCD\). Colon capsule endoscopy \(CCE\) \(L38807\)](#)
 - [Billing and Coding. Colon capsule endoscopy \(CCE\) \(A58414\)](#)
- [Local Coverage Determination \(LCD\). Colon capsule endoscopy \(L38777\)](#)
 - [Billing and Coding. Colon capsule endoscopy \(CCE\) \(A58362\)](#)
 - [Billing and Coding. Colon capsule endoscopy \(A58471\)](#)
- [Local Coverage Determination \(LCD\). Colon capsule endoscopy \(CCE\) \(L38805\)](#)
 - [Billing and Coding. Colon capsule endoscopy \(CCE\) \(A58410\)](#)

- [Local Coverage Determination \(LCD\). Colon capsule endoscopy \(CCE\) \(L38824\)](#)
 - [Billing and Coding. Colon capsule endoscopy \(CCE\) \(A58436\)](#)
- [Local Coverage Determination \(LCD\). Colon capsule endoscopy \(CCE\) \(L38837\)](#)
 - [Billing and Coding. Colon capsule endoscopy \(CCE\) \(A58471\)](#)

Description

Capsule endoscopy involves a patient swallowing a small disposable capsule containing a wireless camera (generally after an overnight fast) that captures images as it passes through the digestive tract and transmits the data to an external recorder. Capsule endoscopy is a non-invasive diagnostic technique that allows for real-time video imaging of the entire gastrointestinal (GI) mucosa, including the esophagus, stomach, ileum, and colon, through a single, non-invasive test (pan-enteric capsule endoscopy), thereby reducing the need for individual invasive tests. Capsule endoscopy is used to detect occult GI bleeding, mucosal abnormalities, and inflammatory bowel disease (IBD), such as Crohn's disease, polyps, tumors, etc., with sensitivity and accuracy that is comparable to optical endoscopy and colonoscopy. However, its major limitations are the standardization of scoring systems, poor specificity, and the lack of transmural and histological assessments.^{1,5,24}

Wireless capsule endoscopy of the small bowel may be requested when a previous upper GI endoscopy and a lower GI colonoscopy do not confirm a source of bleeding. A second capsule endoscopy is typically requested when the initial capsule does not penetrate the pylorus.^{1,5}

Medical Necessity Criteria

Indications

Capsule endoscopy is considered appropriate if **ANY** of the following is **TRUE**^{24,25}:

- Evaluation for **ANY** of the following:
 - Celiac disease with **ANY** of the following^{5,7}:
 - Established celiac disease with symptoms that are persistent or recurrent following a gluten-free diet for at least 6 months^{25,26}; **OR**
 - Suspected celiac disease, when testing shows positive serology and negative duodenal biopsy; **OR**
 - Crohn's disease and **ANY** of the following^{26,27}:
 - Initial diagnosis of suspected Crohn's disease with **ALL** of the following^{3,7}:
 - Absence of definitive evidence of Crohn's disease on at least esophagogastroduodenoscopy (EGD) and colonoscopy, and any other form of imaging (e.g., small bowel follow-through [SBFT], computed tomography [CT] scan, CT enterography, magnetic resonance [MR] enterography); **AND**
 - At least one objective marker of gut inflammation (e.g., elevated white blood cell [WBC] count, erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], fecal calprotectin level, or fecal lactoferrin level); **AND**
 - No contraindication to performing capsule endoscopy (no obstruction or bowel stenosis); **AND**
 - Symptoms raising suspicion for Crohn's (e.g., abdominal pain, weight loss without intent, chronic diarrhea, blood in the stool); **OR**
 - Established diagnosis with **ANY** of the following:
 - Assessment of post-surgical anastomosis is beyond the reach of traditional EGD and ileocolonoscopy when disease recurrence is suspected; **OR**
 - Assessment of small bowel mucosal healing when the index disease distribution has been beyond the reach of traditional EGD and ileocolonoscopy (e.g., jejunum or ileum proximal to the terminal region); **OR**
 - Evaluation of persistent GI symptoms despite Crohn's treatment when traditional EGD and ileocolonoscopy are negative/non-diagnostic for disease activity; **OR**

- GI bleeding with **ANY** of the following^{5,27-30}:
 - For localization of overt or obscure chronic GI bleeding when intraoperative enteroscopy is being considered²⁸; **OR**
 - Overt bleeding (hematochezia or melena) occurring initially or repeatedly and unexplained by at least EGD and colonoscopy, and any other forms of imaging (e.g., push enteroscopy, nuclear scintigraphy, CT, or MR angiography)⁵; **OR**
 - Repeated overt GI bleeding in a patient with prior negative capsule endoscopy, EGD, and colonoscopy²⁸; **OR**
 - Suspected obscure GI bleeding presenting as mild, moderate, or severe iron deficiency anemia that is persistent or recurrent despite adequate iron replacement therapy and remains unexplained by EGD and colonoscopy²⁸; **OR**
 - Suspected obscure GI bleeding presenting as severe iron deficiency anemia (hemoglobin less than 10 gm/dL or requiring intravenous [IV] blood or iron transfusion) that is unexplained by EGD and colonoscopy²⁸; **OR**
- Indeterminate colitis exists, and a more specific diagnosis is sought via small bowel evaluation⁵; **OR**
- Malabsorption syndrome, chronic diarrhea, or protein-losing enteropathy of obscure origin when it is suspected to originate in the small intestinal mucosa with documented appropriate prior negative or non-diagnostic evaluations of the esophagus, stomach, duodenum/small intestine, and colon by flexible endoscopy, and complementary radiologic procedures and/or microbiologic studies³; **OR**
- Regional non-metastatic carcinoid tumors of the small bowel in a patient with carcinoid syndrome⁷; **OR**
- Risks for optical colonoscopy or moderate sedation and **ANY** of the following^{9,11,13,15,18,20,22}:
 - Primary procedure with **ANY** of the following:
 - Fecal Occult Blood Test (FOBT) positive (guaiac or immunochemical); **OR**
 - Multitarget Stool DNA (sDNA) test positive; **OR**
 - Other evidence of lower GI bleeding in hemodynamically stable patients; **OR**
 - Secondary procedure for **ANY** of the following:

- For the detection or surveillance of colon polyp(s) if the diagnostic optical colonoscopy was incomplete; **OR**
- When an incomplete diagnostic optical colonoscopy was performed with **ANY** of the following:
 - FOBT positive (guaiac or immunochemical); **OR**
 - Multitarget sDNA test positive; **OR**
 - Other evidence of lower GI bleeding in hemodynamically stable patients; **OR**
- Screening, evaluation, or surveillance of esophageal varices in a patient with known cirrhosis or portal hypertension when EGD or sedation are prohibited due to medical risk (repeat evaluation in three-year intervals for those without varices; one to two years for a patient with small varices³¹; repeat evaluation is not reasonable for a patient with medium to large varices)^{3,5,7}; **OR**
- Surveillance of small intestinal tumors (e.g., Lynch syndrome, Peutz-Jeghers syndrome, juvenile polyposis syndrome, familial adenomatous polyposis, and other polyposis syndromes affecting the small bowel) at a frequency of every 1 year if small bowel neoplasms have been detected previously, or every two to three years if they have not.^{7,32}

Non-Indications

Capsule endoscopy is not considered appropriate if **ANY** of the following is **TRUE**:

- For services using a device that is not approved by the United States Food & Drug Administration (FDA)^{1,3,5,7}; **OR**
- Repeat procedure to verify the effectiveness of surgery, except when related to Crohn's disease⁷; **OR**
- **ANY** of the following:
 - Allergy to any medication or preparation agent used before or during the procedure^{9,11,13,15,18,20,22}; **OR**
 - Confirmation of lesions or pathology normally within the reach of upper and lower endoscopes (proximal to the ligament of Treitz, or distal to the ileum)^{1,3,5,7}; **OR**
 - Current pregnancy^{5,7}; **OR**
 - Dysphagia or swallowing disorders^{3,5,9,11,13,15,18,20,22}; **OR**
 - Evaluation of **ANY** of the following:
 - Diseases involving the esophagus (other than esophageal varices)⁷; **OR**

- Duodenal lymphocytosis; **OR**
- Gastric varices³³; **OR**
- Gastroesophageal reflux disease (GERD)³; **OR**
- GI bleeding⁷; **OR**
- Hookworms; **OR**
- Irritable bowel syndrome (IBS), suspected; **OR**
- Mucosal inflammation in ulcerative colitis^{34,35}; **OR**
- Small bowel disease other than Crohn's or celiac disease⁷; **OR**
- GI obstruction or small bowel stenosis/stricture, unless a previous patency capsule study was performed and negative for retention^{5,9,11,13,15,18,20,22}; **OR**
- Patency capsule testing³; **OR**
- Performed in conjunction with computed tomography colonography (CTC)^{9,11,13,15,18,20,22}; **OR**
- Routine small bowel investigation in patients with sporadic and nonsporadic duodenal adenomas³⁶; **OR**
- Screening test (other than esophageal varices)^{15,22}; **OR**
- Screening for colorectal cancer, regardless of family history or other risk factors for the development of colonic disease^{1,3,5,7,9,11,13,15,18,20,22}; **OR**
- Second capsule administered per episode of illness unless it was to guarantee an adequate examination (e.g., the initial capsule does not penetrate the pylorus).⁵

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
91113	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for capsule endoscopy may include:

- Adverse events in patients undergoing capsule endoscopy are rare but may include technical problems (e.g., gaps in recordings, short duration of capsule battery, and failure to download data) and clinical problems (e.g., difficulty/inability to swallow the capsule and incomplete small-bowel examination).²⁴
- Due to abnormalities in gastrointestinal (GI) motility or narrowing of the GI tract, an endoscopic capsule may get stuck in the GI tract instead of passing out of the body with normal bowel movements. In such cases, endoscopic or surgical intervention may be required to retrieve the capsule.²⁹
- While standard bowel preparation protocols effectively clear the small bowel in preparation for capsule endoscopy, adequate colonic cleansing remains a challenge.^{37,38}

- Delays in diagnosis due to the lengthy reading times hinder the broader implementation of CE, a drawback that could be overcome through the integration of artificial intelligence (AI) models.³⁹
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for capsule endoscopy may include:

- Improved patient selection includes the appropriate allocation of healthcare resources at the individual beneficiary and population levels.
- Capsule endoscopy provides a comprehensive, non-invasive, and painless technique for diagnosing abnormalities throughout the gastrointestinal (GI) tract.⁴⁰
- Studies have shown a high degree of diagnostic accuracy, sensitivity, and specificity for pan-enteric capsule endoscopy (PCE) compared to conventional endoscopy, intestinal ultrasound, and magnetic resonance enterography (MRE). PCE also shows a trend toward improved diagnostic yield in Crohn's disease and ulcerative colitis.⁴⁰
- Capsule endoscopy has increased the diagnostic yield because it can visualize nearly the entire GI tract. Due to the length and tortuosity of the GI tract, identifying localized lesions or sources of bleeding has been elusive using standard techniques.²⁸
- Capsule endoscopy avoids the need for insufflation or sedation and its associated risks.
- Periodic small bowel inspection with CE is beneficial in detecting intestinal polyps in patients with GI polyposis syndromes, such as patients with Peutz-Jeghers syndrome.³⁶
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Tamilarasan et al. (2022) conducted a systematic review and meta-analysis to compare the diagnostic accuracy of pan-enteric capsule endoscopy (PCE) with conventional endoscopy, intestinal ultrasound, and magnetic resonance enterography (MRE). Analyzing 14 comparative studies, including seven studies evaluating PCE diagnostic yield in Crohn's disease and seven in ulcerative colitis, the authors identified a trend to superiority of PCE over MRE and colonoscopy, with a pooled odds ratio of 1.25 for the detection of Crohn's disease, which indicates an increased diagnostic yield of 5% and 7% for PCE compared to that of MRE and colonoscopy, respectively. Moreover, PCE showed a diagnostic sensitivity of 93.8% and a specificity of 69.8% for detecting ulcerative colitis. The authors concluded that PCE has a comparable diagnostic yield to colonoscopy and MRE for Crohn's disease.⁴⁰

Rosa et al. (2023) conducted a systematic review and meta-analysis on 26 observational studies and five randomized controlled trials (RCTs) involving a total of 4,072 patients to evaluate the efficacy of bowel preparation protocols for capsule colonoscopy. By evaluating multiple steps of the cleansing protocol (diet, adjunctive laxatives, purgative solutions, prokinetic agents, and boosters), the authors identified strategies associated with a higher adequate cleansing rate (ACR) and complete examinations, the main quality outcomes for capsule colonoscopy and pan-intestinal capsule endoscopy. Regression analysis revealed that the highest ACR was obtained using a low-fiber diet, adjunctive laxatives, and a split dose of the purgative polyethylene glycol (PEG, less than four liters). The highest complete examinations were observed using routine prokinetics before swallowing the capsule and using sodium phosphate as a booster.³⁸

Geropoulos et al. (2021) conducted a systematic review and meta-analysis of seven studies with a total of 916 patients to assess the performance of magnetically controlled capsule endoscopy and evaluate its potential in diagnosing gastric lesions. The overall sensitivity of CE was 87%, and subgroup analysis showed that its sensitivity was 82% in detecting gastric ulcers, 82% in detecting gastric polyps, and 95% in detecting gastric erosions. The authors also noted that CE was well-tolerated with minimal adverse events.^{[37](#)}

Enns et al. (2017) performed a systematic review to identify 21 statements regarding the use of capsule endoscopy for patients with Crohn's disease. It is recommended for patients with unexplained symptoms of celiac disease, and treatment is unsuccessful. Capsule endoscopy is also recommended when there is overt gastrointestinal bleeding with negative findings on esophagogastroduodenoscopy and colonoscopy. Select patients may benefit from capsule endoscopy, including those with unexplained chronic anemia or small bowel cancer.^{[25](#)}

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Review History		
Version 1.1	03/18/2025	Updated policy per CMS revisions for 03/06/2025. Updated Effective Date. Updated links and bookmarks.
Version 2	12/11/2025	Annual review. Rewrote indication and non-indication language throughout policy to align with CMS Local Coverage Determinations (LCDs) L33774, L34081, L35089, L36427, L38571, L38755, L38777, L38805, L38807, L38824, and L38837.
Version 2.1	03/17/2026	Revision. Updated link and reference for L34081 and A56461.



Cohere Medical Policy – Capsule Endoscopy

Clinical Guidelines for Medical Necessity Review

Version: 2
Effective Date: January 9, 2025

Important Notices

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Medical Necessity Criteria

Service: Capsule Endoscopy

Recommended Clinical Approach

Capsule endoscopy (CE) involves a patient swallowing a small disposable capsule containing a wireless camera (generally after an overnight fast). It takes images as it passes through the digestive tract and transmits the data to an external recorder. CE is a non-invasive diagnostic technique that allows real-time video imaging of the entire gastrointestinal (GI) mucosa (pan-enteric CE), reducing the need for individual invasive tests to assess the esophagus, stomach, ileum, and colon. CE is used to detect occult GI bleeding mucosal abnormalities and inflammatory bowel disease (IBD), such as Crohn's disease, polyps, tumors, etc., with sensitivity and accuracy comparable to optical endoscopy and colonoscopy. However, its major limitations are the standardization of scoring systems, poor specificity, and the lack of transmural and histological assessments.¹⁻⁴

Wireless capsule endoscopy of the small bowel may be requested when a previous upper GI endoscopy and a lower GI colonoscopy do not confirm a source of bleeding. A second capsule endoscopy is typically requested when the initial capsule does not penetrate the pylorus. Capsule endoscopy is not recommended in patients with a GI blockage, narrowing, or motility disorder.²⁻³

Medical Necessity Criteria

Indications

→ **Capsule endoscopy** is considered appropriate if **ANY** of the following are **TRUE**⁴⁻⁸:

- ◆ Evaluation of a patient with an established diagnosis of celiac disease and symptoms that are persistent or recurrent following a gluten-free diet for at least 6 months^{5,9-12}; **OR**
- ◆ Evaluation of Crohn's disease if **ANY** of the following is **TRUE**^{2,9-10,13-15}:
 - Suspected Crohn's Disease; **OR**

- No evidence of Crohn's disease is found by conventional diagnostic tests (including, but not limited to, small bowel follow-through (SBFT), abdominal computed tomography (CT) / CT enterography, magnetic resonance enterography (MRE), or EGD and ileocolonoscopy) but suspicion of the disease remains; **OR**
- ◆ Re-evaluation of established Crohn's disease when **ANY** of the following is **TRUE**:
 - Despite treatment, symptoms persist and are unexplained by ileocolonoscopy or conventional diagnostic tests; **OR**
 - Assessment of mucosal healing when disease distribution has been beyond the extent of ileocolonoscopy (i.e., jejunal or ileal, beyond terminal ileum); **OR**
 - When disease recurrence is suspected after bowel resection and is not sufficiently characterized by ileocolonoscopy and imaging studies; **OR**
- ◆ For screening or surveillance of esophageal varices in patients with known cirrhosis or portal hypertension when EGD and sedation are prohibited due to medical risk^{2,10,16,25}; **OR**
- ◆ For surveillance of small bowel neoplasia in patients with a GI polyposis syndrome (e.g., familial adenomatous polyposis, Peutz-Jeghers syndrome, Lynch syndrome)^{10,17,30}; **OR**
- ◆ Evaluation of GI bleeding with **ANY** of the following^{3,18,20,22-23,27}:
 - Documented overt GI bleeding (melena or hematochezia, but not hematemesis) that is unexplained by EGD and colonoscopy performed following adequate preparation; **OR**
 - Repeated overt GI bleeding in a patient with prior negative capsule endoscopy, EGD, and colonoscopy; **OR**
 - Suspected obscure GI bleeding presenting as severe iron deficiency anemia (hemoglobin less than 10 gm/dL or requiring intravenous [IV] blood or iron transfusion) that is unexplained by EGD and colonoscopy; **OR**
 - Suspected obscure GI bleeding presenting as mild, moderate, or severe iron deficiency anemia that is persistent or recurrent despite adequate iron replacement therapy and remains unexplained by EGD and colonoscopy; **OR**

- For localization of overt or obscure chronic GI bleeding when intraoperative enteroscopy is being considered; **OR**
- ◆ Evaluation of locoregional non-metastatic carcinoid tumors of the small bowel in persons with carcinoid syndrome when **ALL** of the following are **TRUE**¹⁰:
 - Persistent clinical symptoms (e.g., abdominal pain, anemia, gastrointestinal bleeding, unexplained weight loss); **AND**
 - Failure to determine the etiology of symptoms within 12 months from the onset of symptoms using standard diagnostic testing (including, but not limited to, EGD, colonoscopy, CT, MRE, dotatate PET [postiron emission tomography] scan); **OR**
- ◆ Evaluation of gastric lesions when **ALL** of the following are **TRUE**^{24,26}:
 - Standard diagnostic EGD and sedation are contraindicated; **AND**
 - Magnetically-controlled video capsule device is available and utilized for indication; **AND**
 - Gastric ulcer, polyp, or erosion is suspected; **OR**
- ◆ Evaluation of the colon when **ANY** of the following is **TRUE**^{5,25}:
 - When a prior colonoscopy was unable to reach the cecum after adequate preparation; **OR**
 - When colonoscopy is contraindicated due to excessive risk from conscious or deep sedation as documented by a qualified practitioner (anesthetist, gastroenterologist, surgeon, or other adequately trained endoscopist) and **ANY** of the following:
 - The procedure is for surveillance of cancer/polyps; **OR**
 - Positive stool-based screening test (multitarget stool DNA [mt-sDNA], fecal occult blood test [FOBT], or fecal immunohistochemical test [FIT]); **OR**
 - Other evidence of lower GI bleeding in a hemodynamically stable patient; **OR**
- ◆ For surveillance of graft versus host disease when conventional imaging or endoscopy are insufficient or not tolerated by the patient.²⁰

Non-Indications

→ **Capsule endoscopy** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ The patient has **ANY** of the following:

- Implanted electrical defibrillators that emit a radiofrequency or other interfering signal^{2,10,25}; **OR**
 - Current pregnancy¹⁰; **OR**
 - Dysphagia or swallowing disorders^{3,25}; **OR**
 - GI obstruction, stenosis, stricture, or fistulas based on the clinical picture or pre-procedure testing^{2-3,25}; **OR**
 - Extensive small intestinal diverticulosis²⁰⁻²¹; **OR**
 - Zenker (hypopharyngeal) diverticulum²¹⁻²²; **OR**
 - Allergy to any medication or preparation agent used before or during the procedure²⁵; **OR**
- ◆ The procedure is **ANY** of the following⁹:
- A repeat procedure to verify the effectiveness of surgery, except when related to Crohn's disease; **OR**
 - A screening test (other than esophageal varices); **OR**
 - For colorectal cancer screening regardless of family history or other risk factors for the development of colonic disease^{2-3,25}; **OR**
 - An initial test for diagnosing GI bleeding; **OR**
 - For evaluation of intussusception; **OR**
 - For evaluation of diseases involving the esophagus (other than esophageal varices); **OR**
 - For confirmation of pathology that is sufficiently characterized by other diagnostic means; **OR**
 - For confirmation of lesions or pathology generally within the reach of upper and lower endoscopes (proximal to the ligament of Treitz, or distal to the ileum)²; **OR**
 - To be performed in conjunction with computed tomography colonography (CTC)²⁵; **OR**
 - For investigation of **ANY** of the following:
 - Duodenal lymphocytosis; **OR**
 - Suspected irritable bowel syndrome (IBS)²⁸; **OR**
 - For routine small bowel investigation in patients with sporadic and nonsporadic duodenal adenomas³⁰; **OR**
 - For detecting gastric varices; **OR**
 - For detecting hookworms; **OR**
 - For diagnosing or evaluating mucosal inflammation in ulcerative colitis.

Level of Care Criteria

Inpatient or outpatient.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report

Medical Evidence

Tamilarasan et al. (2022) conducted a systematic review and meta-analysis to compare the diagnostic accuracy of pan-enteric capsule endoscopy (PCE) with conventional endoscopy, intestinal ultrasound, and magnetic enterography (MRE). Analyzing 14 comparative studies, including 7 studies evaluating PCE diagnostic yield in Crohn's disease (CD) and 7 in ulcerative colitis (UC), the authors identified a trend to superiority of PCE over MRE and colonoscopy, with a pooled odds ratio of 1.25 for the detection of CD, which indicates an increased diagnostic yield of 5% and 7% for PCE compared to that of MRE and colonoscopy, respectively. Moreover, PCE showed a diagnostic sensitivity of 93.8% and a specificity of 69.8% for detecting UC. The authors concluded that PCE has a comparable diagnostic yield to colonoscopy and MRE for CD.¹

Rosa et al. (2023) conducted a systematic review and meta-analysis on 26 observational studies and 5 randomized controlled trials (RCTs) involving a total of 4,072 patients to evaluate the efficacy of bowel preparation protocols for capsule colonoscopy. By evaluating multiple steps of the cleansing protocol (viz., diet, adjunctive laxatives, purgative solutions, prokinetic agents, and boosters), the authors identified strategies associated with higher rates of adequate cleansing (ACR) and complete examinations (CR), the main quality outcomes for capsule colonoscopy and pan-intestinal capsule endoscopy. Regression analysis revealed that the highest ACR was obtained using a low-fiber diet, adjunctive laxatives, and a split dose of the purgative polyethylene glycol (PEG, less than 4 liters). The highest CR was observed using routine prokinetics before swallowing the capsule and using sodium phosphate as a booster.²⁹

Geropulos et al. (2021) conducted a systematic review and meta-analysis of 7 studies with a total of 916 patients to assess the performance of magnetically controlled capsule endoscopy and evaluate its potential in diagnosing gastric lesions. The overall sensitivity of CE was 87%, and subgroup analysis showed that its sensitivity was 82% in detecting gastric ulcers, 82% in detecting gastric polyps, and 95% in detecting gastric erosions. The authors also noted that CE was well tolerated with minimal adverse events.²⁶

Enns et al. (2017) performed a systematic review to identify 21 statements regarding the use of capsule endoscopy for patients with Crohn's disease. It is recommended for patients with unexplained symptoms of celiac disease and treatment is unsuccessful. Capsule endoscopy is also recommended when there is overt gastrointestinal bleeding with negative findings on

esophagogastroduodenoscopy and colonoscopy. Select patients may benefit from capsule endoscopy, including those with unexplained chronic anemia or small bowel cancer.⁵

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Clinical Guideline Revision History/Information

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Version 2	1/9/2025	• Annual Review • 91111 and 91113 CPT codes added • Indications updated: ○ Repeat procedure criterion ○ Endoscopy changed to ileocolonoscopy for greater specificity; ○ Need for magnetically controlled capsule discussed and retained; ○ Addition of ulcerative colitis and indeterminate colitis indications discussed and discarded; ○ Graft vs host surveillance added ○ Dotatate PET scan added as standard diagnostics for carcinoid syndrome • Non-indications updated ○ Diagnosis of Takayasu's removed ○ Repeat procedure clarified with exception in the case of Crohn's disease • Medical evidence updated • References updated



Cohere Medicare Advantage Policy – Esophagogastroduodenoscopy (EGD)

Clinical Policy for Medical Necessity Review

Version: 3

Policy Number: CHP-022-3

Cohere Health UMC Approval Date: January 29, 2026

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Next Annual Review: January 29, 2027

Important Notices

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Policy Information:

Specialty Area: Gastroenterology

Policy Name: Cohere Medicare Advantage Policy - Esophagogastroduodenoscopy (EGD)

Policy Number: CHP-022-3

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Esophagogastroduodenoscopy (EGD)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁷

- [National Coverage Determination \(NCD\). Endoscopy \(100.2\)](#)
- [Local Coverage Determination \(LCD\). Diagnostic and therapeutic esophagogastroduodenoscopy \(L33583\)](#)
 - [Billing and Coding: Diagnostic and therapeutic esophagogastroduodenoscopy \(A57063\)](#)
- [Local Coverage Determination \(LCD\). Upper gastrointestinal endoscopy and visualization \(L34434\)](#)
 - [Billing and Coding: Upper gastrointestinal endoscopy and visualization \(A56389\)](#)
- [Local Coverage Determination \(LCD\). Upper gastrointestinal endoscopy \(diagnostic and therapeutic\) \(L35350\)](#)
 - [Billing and Coding: Upper gastrointestinal endoscopy \(diagnostic and therapeutic\) \(A57414\)](#)

Description

Esophagogastroduodenoscopy (EGD) is an upper intestinal endoscopy technique used to examine, obtain samples, or treat pathological conditions of the upper intestinal tract. EGD is performed with a lighted, flexible, fiberoptic instrument, usually less than 12 mm in diameter, passed through the cricopharynx. The patient receives conscious sedation, and a topical anesthetic may be applied to the posterior pharynx. The entire esophagus, stomach, and duodenum can be visualized with EGD. Endoscopic ultrasound (EUS) or transendoscopic ultrasound utilizes a transducer at the end of an endoscope to obtain high-resolution images, enhancing visualization of the gastrointestinal tract and enabling evaluation of adjacent structures, including the pancreas and biliary tree.

Diagnostic EGD is used to visualize the oropharynx, esophagus, stomach, and proximal duodenum and is useful for detecting conditions such as benign or malignant focal lesions, diffuse mucosal changes, luminal obstruction, abnormal motility, and extrinsic compression by contiguous structures.⁸ A diagnostic EGD allows the examiner to visualize abnormalities detectable by the technique and to photograph and collect a biopsy sample as appropriate. An endoscopic Doppler probe can be used as an adjunctive diagnostic modality to assess the local blood supply efficacy of the treatment and to stratify patients at higher risk of repeat upper gastrointestinal bleeding (UGIB). Pulsatile Doppler signals can indicate the presence and path of bleeding vessels. The probe can also determine if vessels were appropriately coagulated following endoscopic hemostasis. The absence of a Doppler signal is consistent with successful hemostasis of a bleeding lesion. Lesions with a persistent Dopplerable signal have a higher risk for rebleeding.⁹

EGD is generally considered a safe procedure, although bleeding, perforation, infection, acute pancreatitis¹⁰, and sedation-related complications¹¹ following the procedure have been reported in rare instances.¹²

Medical Necessity Criteria

Indications

An **esophagogastroduodenoscopy (EGD)** is considered appropriate if **ANY** of the following is **TRUE**¹:

- Single screening exam for gastroesophageal reflux disease (GERD) with **AT LEAST THREE** of the following risk factors for concurrent Barrett's esophagus⁸:
 - Age of the patient is greater than 50 years; **OR**
 - Current or past tobacco use; **OR**
 - Family history of Barrett's esophagus in a first-degree relative; **OR**
 - Family history of esophageal adenocarcinoma in a first-degree relative; **OR**
 - Hiatal hernia¹³; **OR**
 - Male gender; **OR**
 - Obesity; **OR**
- Upper abdominal distress^A with **ANY** of the following:
 - Any alarm sign or symptom^B; **OR**
 - Equivocal result from non-invasive test for *Helicobacter pylori* and need for gastric biopsy; **OR**
 - Palpable abdominal mass; **OR**
 - Persistent or recurrent symptoms despite appropriate medical therapy^C; **OR**
 - Presence of lymphadenopathy (e.g., supraclavicular, periumbilical, etc.); **OR**
- Barrett's esophagus is present, and the patient requires **ANY** of the following:
 - Reassessment during treatment to eliminate dysplasia (e.g., ablation, mucosal resection, mucosal dissection) every 2 to 6 months¹⁴; **OR**
 - Routine surveillance of non-dysplastic disease every 12 to 24 months^{8,15}; **OR**
 - Surveillance after completion of treatment for dysplasia or if treatment of dysplasia is deferred, with **ANY** of the following⁸:
 - High-grade dysplasia (every 3 months for 1 year, then every 6 months for 1 year, then annually thereafter); **OR**
 - Low-grade dysplasia (every 6 months for 1 year, then annually thereafter); **OR**

- Acute injury, including ingestion of **ANY** of the following:
 - Caustic agent to determine extent of severity^{2,4,6,16,17}; **OR**
 - Sharp foreign object or food bolus^{2,4,6,16,18}; **OR**
- Celiac disease with **ANY** of the following:
 - Known celiac disease with **ANY** of the following¹⁹:
 - The patient has been on a gluten-free diet for at least 1 year and requires histologic confirmation of remission; **OR**
 - Symptoms persist despite adherence to a gluten-free diet for at least 6 months; **OR**
 - Suspected celiac disease based on **ANY** of the following¹⁹:
 - Abnormally elevated celiac serology, including **ANY** of the following:
 - Deamidated anti-gliadin IgG with IgA deficiency; **OR**
 - Endomysial IgA with normal total IgA; **OR**
 - Tissue transglutaminase immunoglobulin A (TTG IgA) with normal total IgA; **OR**
 - High-risk based on celiac human leucocyte antigen (HLA) analysis; **OR**
 - Typical alarm signs or symptoms^B; **OR**
- Atypical chest pain after cardiac disease has been ruled out²⁰; **OR**
- Clarification of location or pathology of a lesion during surgery^{4,6,21}; **OR**
- Conditions in which upper gastrointestinal (GI) pathology might modify other planned management, including **ANY** of the following^{4,6,16}:
 - Bariatric surgery is scheduled⁴; **OR**
 - Cancer of the head or neck⁴; **OR**
 - Long-term anticoagulation therapy^{4,6}; **OR**
 - Long-term nonsteroidal anti-inflammatory drug therapy for arthritis^{4,6}; **OR**
 - Organ transplantation is scheduled^{4,6}; **OR**
- Confirmation and specific histologic diagnosis of radiologically demonstrated lesions, including **ANY** of the following^{2,4,6,22,23}:
 - A lesion that requires biopsy for diagnosis^{2,4,6}; **OR**
 - Excavated lesions (e.g., erosions, ulcers, obstructions, or diverticula)^{2,4,16}; **OR**
 - Other mucosal abnormalities^{D,2,4}; **OR**
 - Protrusions/growths from, within, or extrinsic to the mucosal wall; **OR**
- Eosinophilic esophagitis (EoE) (confirmed or suspected) for **ANY** of the following²⁴:

- Examination for suspected EoE for evaluation of **ANY** of the following:
 - Dysphagia; **OR**
 - GERD symptoms refractory to proton pump inhibitor (PPI) therapy; **OR**
 - History of esophageal food bolus impaction; **OR**
- Follow-up exam to reassess esophageal histology for confirmed EoE, after treatment^E; **OR**
- Follow-up exam to reassess the esophagus when symptoms recur on previously effective therapy; **OR**
- Erosive reflux esophagitis with **ANY** of the following²⁵:
 - Documentation of healing after treatment of Los Angeles (LA) grade C or D esophagitis and to exclude the development of Barrett's esophagus; **OR**
 - Persistent or recurrent symptoms despite appropriate GERD treatment; **OR**
- Esophageal dysmotility based on barium radiography or esophageal manometry, when suggestive of achalasia²²; **OR**
- Evaluation for **ANY** of the following:
 - Chronic diarrhea to identify an upper GI etiology when small bowel disease is suspected⁴; **OR**
 - Esophagogastric varices due to suspicion for or confirmation of liver cirrhosis or portal hypertension^{4,6,16,26}; **OR**
 - GI bleeding and **ANY** of the following:
 - Active bleeding is present (e.g., hematemesis, melena, or hematochezia)^{2,4,6,16}; **OR**
 - Presumed chronic blood loss^F (e.g., iron deficiency anemia) when colonoscopy is negative for a definitive etiology^{2,4,6,16}; **OR**
 - Re-bleeding occurs after recent endoscopic therapy^{4,6}; **OR**
 - Recent active bleeding (within 72 hours) with unknown etiology; **OR**
 - Surgery is being considered^{2,4,6}; **OR**
 - Suspected aorto-enteric fistula (AEF)⁴; **OR**
 - Upper GI symptoms; **OR**
 - Possible gastric or duodenal polyps in patients with familial adenomatous polyposis or other at-risk hereditary syndromes^{6,16,27}; **OR**
- Persistent or recurrent GERD symptoms^H despite appropriate therapy^{C,28}; **OR**
- Heartburn with **ANY** of the following:
 - Any alarm symptom^B; **OR**

- The patient is 40 years of age or greater with a significant history of heartburn that returns after a course of symptomatic therapy²; **OR**
- Pediatric patient with **ANY** of the following:
 - Abdominal pain with suspicion of an organic disease²⁹; **OR**
 - Anemia, unexplained^{2,29}; **OR**
 - Caustic ingestion^{2,4,6,16,17,29}; **OR**
 - Chronic diarrhea, unexplained²⁹; **OR**
 - Dysphagia or odynophagia^{4,6,16,29}; **OR**
 - Esophagitis (eosinophilic or infectious)³⁰; **OR**
 - GERD (chronic) to exclude other diseases^{29,30}; **OR**
 - Hematemesis^{29,30}; **OR**
 - Hematochezia²⁹; **OR**
 - Surveillance of Barrett's esophagus^{16,29,30}; **OR**
 - Suspicion of graft versus host disease²⁹; **OR**
 - Vomiting that is recurrent with unknown cause²⁹; **OR**
 - Weight loss or failure to thrive²⁹; **OR**
- Peptic ulcer disease with **ANY** of the following²⁵:
 - Follow-up of duodenal ulcer or other lesions of the upper gastrointestinal tract that have resulted in serious consequences (e.g., hemorrhage)⁶; **OR**
 - Follow-up of esophageal, gastric, or stomal ulcers to demonstrate healing (frequency of follow-up EGDs is variable, but every two to four months until healing is demonstrated is reasonable)^{2,6}; **OR**
 - Persistent or recurrent symptoms despite treatment; **OR**
- Planning for anti-reflux surgery^{2,31}; **OR**
- Routine screening (every 3 years) or surveillance (every 1 to 2 years) of non-bleeding esophagogastric varices²⁶; **OR**
- Sampling to obtain tissue or fluid from **ANY** of the following^{4,6}:
 - Duodenum; **OR**
 - Jejunum; **OR**
- Serial follow-up of **ANY** of the following²:
 - After polypectomy for adenomatous gastric lesions (frequency of every 6 months to 4 years, depending on clinical circumstances and original polyp morphology); **OR**
 - Esophageal varices or bleeding lesions requiring recurrent therapy; **OR**
 - Removal of percutaneous gastrostomy tube (PEG)¹; **OR**
 - Treatment of esophageal strictures requiring guidewire dilation; **OR**

- Surveillance as determined by the endoscopist for or suspected recurrence of prior upper GI cancer or pre-cancer, including **ANY** of the following²⁵:
 - **ANY** of the following adenocarcinomas³²:
 - Duodenum or ampulla; **OR**
 - Esophagus; **OR**
 - Mucosa-associated lymphoma (MALT) of the stomach; **OR**
 - Adenomatous polyp of the stomach, duodenum, or ampulla⁶; **OR**
 - Dysplasia (low or high grade) in patients with gastric intestinal metaplasia or chronic atrophic gastritis¹⁶; **OR**
 - Other subepithelial pre-malignant lesion of the esophagus, stomach, or duodenum³³; **OR**
 - Squamous cell carcinoma of the esophagus³⁴; **OR**
 - Stromal/neuroendocrine tumor of the esophagus, stomach, or duodenum³⁵; **OR**
- Suspected inflammation of the upper gastrointestinal (GI) tract from etiologies such as inflammatory myositis, Crohn's disease, ulcerative colitis, inflammatory bowel disease (IBD), acute graft versus host disease^{36,37}; **OR**
- Therapeutic treatment of **ANY** of the following:
 - Bleeding from upper GI lesions (e.g., ulcers, tumors, vascular malformations [injection therapy, thermal coagulation, band ligation])⁶; **OR**
 - Dilatation of strictures in the upper intestinal tract^{2,6}; **OR**
 - Endoscopic therapy of intestinal metaplasia⁴; **OR**
 - Feeding tube placement (oral, percutaneous endoscopic gastrostomy, percutaneous endoscopic jejunostomy)^{2,6}; **OR**
 - Management of achalasia (e.g., pneumatic balloon dilation, botulinum toxin injection, or per oral endoscopic myotomy); **OR**
 - Management of operative complications^{1,4}; **OR**
 - Palliative therapy of stenosing neoplasms^{2,4,6}; **OR**
 - Removal of selected polypoid or neoplastic lesions^{2,4,6}; **OR**
 - Sclerotherapy and/or band ligation for bleeding from esophageal or gastric varices^{2,4,6}; **OR**
- Unexplained weight loss³⁸; **OR**
- Vomiting that is persistent and unexplained^{2,4,6,16,38}; **OR**
- EGD with endoscopic ultrasound and **ANY** of the following^{2,4,6}:

- Evaluation of abnormalities or structures within or adjacent to **ANY** of the following:
 - Biliary tree; **OR**
 - Gallbladder; **OR**
 - GI tract wall; **OR**
 - Liver; **OR**
 - Mediastinum; **OR**
 - Pancreas (e.g., masses, pseudocysts, chronic pancreatitis); **OR**
 - Thoracic or abdominal lymph nodes; **OR**
- Providing access (independently or as an adjunct to endoscopic retrograde cholangiopancreatography [ERCP]) to **ANY** of the following:
 - Bile ducts; **OR**
 - Pancreatic duct; **OR**
- Providing endoscopic therapy of the GI tract under ultrasonographic guidance; **OR**
- Staging of tumors known to be metastatic, when EUS results might alter cancer treatment decision-making; **OR**
- Staging tumors of the GI tract, pancreas, and bile ducts; **OR**
- Tissue sampling of lesions within, or adjacent to, the wall of the GI tract; **OR**
- Transmural delivery of targeted cancer treatment (e.g., radiofrequency ablation, chemotherapy); **OR**
- Transmural injection of therapeutic agents (e.g., ethanol, phenol), including **ANY** of the following:
 - Botulinum toxin into the esophageal muscularis for treatment of achalasia⁴; **OR**
 - Neurolytic agent (e.g., botulinum toxin, ethanol, phenol) into the celiac plexus for **ANY** of the following:
 - Identify/predict surgical success in patients with median arcuate ligament syndrome (MALS); **OR**
 - Palliate chronic pain related to upper abdominal cancer (e.g., pancreatic cancer); **OR**
 - Relieve chronic pain related to chronic pancreatitis that is unresponsive to medical therapy; **OR**
- Transmural placement of fiducial markers in tumors for surveillance or presurgical marking.

Non-Indications

An **esophagogastroduodenoscopy (EGD)** is not considered appropriate if **ANY** of the following is **TRUE**¹:

- Radiologic imaging with report that demonstrates **ANY** of the following^{6,16}:
 - Deformed duodenal bulb with **ANY** of the following:
 - Absence of symptoms; **OR**
 - The patient responded adequately to ulcer therapy; **OR**
 - Sliding hiatal hernia (asymptomatic or uncomplicated); **OR**
 - Uncomplicated duodenal ulcer that has responded to therapy; **OR**
- Absence of GI symptoms when a patient is undergoing unrelated elective surgery; **OR**
- Blockage in the esophagus, stomach, or duodenum is previously established; **OR**
- Metastatic adenocarcinoma of unknown primary site, when results will not alter management; **OR**
- Optical endomicroscopy is requested; **OR**
- Pediatric patient with **ANY** of the following²⁹:
 - Diagnosis of a perforation; **OR**
 - Functional GI disorders; **OR**
 - Uncomplicated GERD; **OR**
- Perforated bowel³⁹; **OR**
- Perforated viscus, known or suspected³⁹; **OR**
- Peritonitis⁴⁰; **OR**
- Routine screening in asymptomatic patients; **OR**
- Significant cardiac arrhythmia or recent (within the last 3–6 months) myocardial infarction^{2,8}; **OR**
- Surveillance of **ANY** of the following¹⁶:
 - Cancer in a patient with pernicious anemia, treated achalasia, or prior gastric resection^{2,6,8}; **OR**
 - Healed, benign disease, such as gastric or duodenal ulcer or benign esophageal strictures^{2,6,8}; **OR**
 - Repeated dilations of benign stricture unless there is a change in status (e.g., persistent or recurrent dysphagia)⁶; **OR**
- Symptoms that are functional in origin¹⁶; **OR**
- When lower GI evaluation fully explains symptoms or lab abnormalities.

Definitions & Notes

^AUpper abdominal distress: dyspepsia, further defined as upper abdominal pain, early satiety, nausea, or anorexia

^BAlarm symptoms: anemia, dysphagia/odynophagia, GI bleeding, persistent vomiting, or unexplained weight loss)^{2,4,6,8,16,41}

^CAppropriate medical therapy: H2 receptor antagonist, proton pump inhibitor (PPI), or potassium-competitive acid blockers (PCAB)

^DOther mucosal abnormalities: thickened fold(s) or asymmetric/symmetric narrowing(s) (stenoses/strictures)^{2,4}

^ETreatment prior to a follow-up exam to reassess esophageal histology for confirmed eosinophilic esophagitis (EoE): includes food allergen restriction, PPI therapy, steroid therapy, and anti-interleukin therapy

^FPresumed blood loss: iron deficiency anemia, positive fecal occult blood test, or both^{2,4,6,16}

^GAt-risk hereditary syndromes: includes Lynch syndrome, juvenile polyposis syndrome, Peutz-Jegher's syndrome, MUTYH-Associated Polyposis (MAP), Li-Fraumeni syndrome, Cowden syndrome, hereditary gastric cancer syndrome^{6,16,27}

^HGastroesophageal reflux disease (GERD) symptoms: heartburn, regurgitation, or chest pain that persists despite treatment²⁸

^IPatients undergoing dilations, percutaneous endoscopic gastrostomy (PEG), polypectomy, endoscopic sphincterotomy, endoscopic ultrasound-guided fine-needle aspiration (FNA), laser ablation, and coagulation are at higher risk for bleeding, and adjustment of anticoagulation may be necessary.

^JOperative complications: dilatation of anastomotic strictures, stenting of anastomotic disruption, fistula, or leak in selected circumstances⁴

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural

	injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for diagnostic esophagogastroduodenoscopy (EGD) may include:

- Adverse effects from delayed or denied treatment, such as increased cardiopulmonary-related adverse events, account for over 60% of unplanned events during endoscopy.^{[42,43](#)}
- Other complications include acute pancreatitis^{[44](#)}, sore throat, bleeding, perforation (less than 1 in 2500 cases), missed lesions, sedation-related complications, and dental trauma.^{[42,45](#)}
- Infection may also occur due to translocation of endogenous bacterial flora (including *Escherichia coli*, *Klebsiella*, other *Enterobacteriaceae*, and enterococci) from one patient to another.^{[46](#)}
- To decrease gastrointestinal (GI) peristalsis, the anti-cholinergic agent hyoscine-N-butyl bromide (HBB) is used in GI endoscopy. Side effects of HBB may include sleepiness, vision changes, dry mouth, rapid heart rate, triggering of glaucoma, and severe allergies.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for EGD may include:

- Improved patient selection may lead to better long-term outcomes, including faster and more accurate visualization of inflammation, growths, ulcers, bleeding, and other abnormalities of the upper GI tract.^{[12](#)} Early detection, diagnosis, and surveillance of upper gastrointestinal malignancies.^{[15](#)}

- Alternative EGD techniques, such as nasal EGD, have been considered to reduce patients' discomfort and anxiety and avoid sedation-related adverse effects relative to peroral EGD.¹⁴
- Enhanced overall patient satisfaction and healthcare experience.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Sengupta et al. (2024) documented the recommendations from the American College of Gastroenterology (ACG) and the Society of Abdominal Radiology (SAR). The recommendations focused on a comparison of the advantages and limitations of endoscopic versus radiologic diagnostic examinations in patients with gastrointestinal bleeding. The authors noted that, unless contraindicated, the evaluation of non-variceal upper gastrointestinal bleeding begins with esophagogastroduodenoscopy (EGD), with the ideal timing for the procedure being within 24 hours of presentation due to the increased risk of mortality when performed greater than 24–36 hours.⁴⁷

Guidelines from the ACG and the American Gastroenterological Association (AGA) focused on the use of EGD in high-volume clinical scenarios, including peptic disease, Barrett's esophagus, and celiac disease. The robust guidance is utilized where appropriate in this policy.^{8,19,41}

Coelho et al. (2022) reported on a 2022 American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Review of adverse events associated with EGD. Approximately 7 million EGDs are performed annually in the United States. The ASGE stated that the procedure is well tolerated and safe, and that the overall incidence of the most insidious complications (e.g., perforation, cardiopulmonary sequelae, and bleeding) remained extraordinarily low. The perforation rate is 1 in 25,000. Evaluation of bleeding requiring emergency department care or inpatient stay for resolution was found in 80 of 100,000 patients within 30 days of the EGD.¹²

Van Wanrooij et al. (2022) presented a technical review of endoscopic ultrasound from the European Society of Gastrointestinal Endoscopy (ESGE). The authors discussed several scenarios supporting endoscopic ultrasound as the optimal diagnostic or therapeutic modality. This included drainage of fluid collections, biopsy of suspicious lesions, and surveillance and staging of neoplasms.⁴⁸

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Policy Revision History/Information

Original Date: February 6, 2025		
Review History		
Version 2	03/13/2025	Changed policy title to “Esophagogastroduodenoscopy [EGD]” – prior title was considered less inclusive of the current range of indications. Added previously missing CMS guidance (NCD 100.2, LCD L34434). Modified criteria so as not to be perceived as more stringent than CMS (i.e., loosed surveillance timeframe of non-dysplastic Barrett’s to 1–3 years, utilized CMS language around peptic ulcer disease, simplified, added CMS indication for need for tissue/fluid sampling, simplified definition of “recent bleeding”, utilized CMS indications for therapeutic EGD use, serial follow-up, and esophageal ultrasound). Rewrote the Medical Evidence section for relevance. Added references.
Version 2.1	10/07/2025	Updated CMS link and reference for L34434, A57063, A57414, and A56389– no content change Re-formatted document to the current template version.

Version 3	01/29/2026	Annual review. Rearranged bullets for improved usability and organization. Removed indication for GERD screening (Prolonged GERD for more than 5 years). Added indication for patients 40 years of age or greater with a significant history of heartburn that returns after a course of symptomatic therapy. Updated indication for the removal of a sharp object or a food bolus. Added pediatric indications. Added indication for therapeutic treatment for feeding tube placement. Added non-indication for advanced imaging that demonstrates a deformed duodenal bulb, sliding hiatal hernia, or uncomplicated duodenal ulcer that has responded to therapy. Added non-indications for pediatric patients. Added non-indication for surveillance of repeated dilations of benign stricture unless there is a change in status. Added non-indication for symptoms that are functional in origin.



Cohere Medicare Advantage Policy – Diagnostic Esophagogastroduodenoscopy (EGD)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: February 6, 2025

Important Notices

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Medical Necessity Criteria

Service: Diagnostic Esophagogastroduodenoscopy (EGD)

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻⁴

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁴

- [Local Coverage Determination \(LCD\). Diagnostic and Therapeutic Esophagogastroduodenoscopy \(L33583\)](#)
- [Billing and Coding: Diagnostic and Therapeutic Esophagogastroduodenoscopy \(A57063\)](#)
- [Local Coverage Determination \(LCD\). Upper Gastrointestinal Endoscopy \(Diagnostic and Therapeutic\) \(L35350\)](#)
- [Billing and Coding: Upper Gastrointestinal Endoscopy \(Diagnostic and Therapeutic\) \(A57414\)](#)

Recommended Clinical Approach

Esophagogastroduodenoscopy (EGD) is an upper intestinal endoscopy technique used to examine, obtain samples, or treat pathological conditions of the upper intestinal tract. EGD is performed with a lighted, flexible, fiberoptic instrument, usually less than 12 mm in diameter, passed through the cricopharynx. The patient receives conscious sedation, and a topical

anesthetic may be applied to the posterior pharynx. The entire esophagus, stomach, and duodenum can be visualized with EGD. Endoscopic ultrasound (EUS) or transendoscopic ultrasound uses a transducer at the end of an endoscope to obtain high-resolution images that improve visualization of the gastrointestinal tract and allow evaluation of adjacent structures, including the pancreas and biliary tree.

Diagnostic EGD is used to visualize the oropharynx, esophagus, stomach, and proximal duodenum and is useful for detecting conditions such as focal benign or malignant lesions, diffuse mucosal changes, luminal obstruction, abnormal motility, and extrinsic compression by contiguous structures.⁵ A diagnostic EGD allows the examiner to visualize abnormalities detectable by the technique and to photograph and collect a biopsy sample as appropriate. An endoscopic Doppler probe can be used as an adjunct diagnostic modality to assess local blood supply and efficacy of treatment and to stratify patients at higher risk of repeat upper gastrointestinal bleeding (UGIB). Pulsatile Doppler signals can indicate the presence and path of bleeding vessels. The probe can also determine if vessels were appropriately coagulated following endoscopic hemostasis. The absence of a Doppler signal is consistent with successful hemostasis of a bleeding lesion. Lesions with a persistent dopplerable signal have a higher risk for rebleeding.⁶

EGD is generally considered a safe procedure, although bleeding, perforation, infection, acute pancreatitis,⁷ and sedation-related complications⁸ following the procedure have been reported in rare instances.⁹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions for diagnostic esophagogastroduodenoscopy (EGD) coverage. This process helps prevent incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Cardiopulmonary-related adverse events account for over 60% of unplanned events during endoscopy.¹⁰
- Sore throat¹⁰
- Bleeding¹⁰
- Perforation (less than 1 in 2,500 cases)
- Infection due to translocation of endogenous bacterial flora (including *Escherichia coli*, *Klebsiella*, other *Enterobacteriaceae*, and enterococci) from one patient to another¹¹
- Acute pancreatitis⁷
- Sedation-related complications^{8,10}
- Dental trauma¹⁰
- To decrease GI peristalsis, the anti-cholinergic agent hyoscine-N-butyl bromide (HBB) is used in gastrointestinal (GI) endoscopy. Side effects of HBB may include sleepiness, vision changes, dry mouth, rapid heart rate, triggering of glaucoma, and severe allergies.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Fast and accurate visualization of inflammation, growths, ulcers, bleeding, and other abnormalities of the upper gastrointestinal (GI) tract.⁵
- Nasal EGD has been considered to reduce patients' discomfort and anxiety and avoid sedation-related adverse effects relative to peroral EGD.¹²
- Early detection, diagnosis, and surveillance of upper gastrointestinal malignancies.¹³
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with minimizing potential harms, providing numerous clinical benefits, and helping avoid unnecessary complications from inappropriate care.

In addition, using these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Diagnostic esophagogastroduodenoscopy (EGD)** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Gastroesophageal reflux disease (GERD) symptoms (e.g., heartburn, regurgitation, or chest pain) that persist despite treatment^{9,14}; **OR**
- ◆ A single screening exam for GERD with **AT LEAST THREE** of the following risk factors for concurrent Barrett's esophagus^{5,9}:
 - Prolonged GERD for more than 5 years; **OR**
 - The age of the patient is greater than 50 years; **OR**
 - Male gender; **OR**
 - Hiatal hernia¹⁵⁻¹⁶;
 - Current or past tobacco use; **OR**
 - Obesity; **OR**
 - Family history of Barrett's esophagus in a first-degree relative; **OR**
 - Family history of esophageal adenocarcinoma in a first-degree relative; **OR**

- ◆ Planning anti-reflux surgery¹⁷; **OR**
- ◆ Nausea that is persistent and unexplained¹⁴; **OR**
- ◆ Vomiting that is persistent and unexplained^{9,14}; **OR**
- ◆ Atypical chest pain after cardiac disease has been ruled out¹⁴; **OR**
- ◆ Heartburn with alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss)^{16,18}; **OR**
- ◆ Prolonged anorexia⁹; **OR**
- ◆ Unexplained weight loss⁹; **OR**
- ◆ Effects of nonsteroidal anti-inflammatory drug (NSAID) use¹⁹; **OR**
- ◆ Barrett's esophagus is present, and the patient requires **ALL** of the following²⁰:
 - Routine surveillance of non-dysplastic disease every 3 to 5 years^{5,21}; **AND**
 - Reassessment during treatment to eliminate dysplasia (e.g., ablation, mucosal resection, mucosal dissection) every 3 to 6 months²⁰; **AND**
 - Surveillance after completion of treatment for dysplasia when **ANY** of the following is **TRUE**⁵:
 - For low-grade dysplasia – every 6 months for 1 year, then annually thereafter; **OR**
 - For high-grade dysplasia – every 3 months for 1 year, then every 6 months for 1 year, then annually thereafter; **OR**
- ◆ Swallowing symptoms including, but not limited to, **ANY** of the following:
 - Difficulty swallowing (e.g., dysphagia); **OR**
 - Pain while swallowing (odynophagia); **OR**
- ◆ Esophageal dysmotility based on barium radiography or esophageal manometry, when suggestive of achalasia²²; **OR**
- ◆ Confirmation and specific histologic diagnosis of radiologically demonstrated lesions, including, but not limited to, **ANY** of the following^{13,22-24}:
 - Protrusions/growths from, within, or extrinsic to the mucosal wall; **OR**

- Excavated lesions, such as erosions, ulcers, or diverticula;
OR
- Other mucosal abnormalities, including thickened fold(s) or asymmetric/symmetric narrowing(s) (stenoses/strictures);
OR
- ◆ Clarification of location or pathology of a lesion during surgery^{3,25};
OR
- ◆ Evaluation for possible gastric or duodenal polyps in patients with familial adenomatous polyposis or other at-risk hereditary syndromes (e.g., Lynch syndrome, juvenile polyposis syndrome, Peutz-Jegher's syndrome, MUTYH-Associated Polyposis [MAP], Li-Fraumeni syndrome, Cowden syndrome, hereditary gastric cancer syndrome)²⁶; **OR**
- ◆ The patient is less than 60 years of age and has dyspepsia with **ANY** of the following:
 - Negative *Helicobacter pylori* test and no response to proton pump inhibitor (PPI) therapy^{14,27-28}; **OR**
 - Equivocal results from non-invasive *Helicobacter pylori* testing and need for gastric biopsy²⁸⁻²⁹; **OR**
 - A one-time screening in a patient with a family history of upper GI malignancy in a first-degree relative; **OR**
 - Lymphadenopathy (e.g., supraclavicular, periumbilical); **OR**
 - Palpable abdominal mass; **OR**
 - Alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss, dysphagia/odynophagia); **OR**
- ◆ The patient is 60 years of age or older and has dyspepsia; **OR**
- ◆ Peptic ulcer disease with **ANY** of the following³⁰⁻³¹:
 - Persistent or recurrent symptoms despite treatment; **OR**
 - Recent identification of gastric or duodenal ulcer, to document ulcer healing after treatment for at least 2 months, even without symptoms; **OR**
- ◆ Erosive reflux esophagitis with **ANY** of the following^{6,30}:
 - Persistent or recurrent symptoms despite appropriate GERD treatment; **OR**

- To document healing after treatment of grade C or D esophagitis and to exclude the development of Barrett's esophagus; **OR**
- ◆ Surveillance as determined by the endoscopist for or suspected recurrence of prior upper GI cancer or pre-cancer, including **ANY** of the following³⁰:
 - Squamous cell carcinoma of the esophagus; **OR**
 - Adenocarcinoma of the esophagus; **OR**
 - Adenocarcinoma or mucosa-associated lymphoma (MALT) of the stomach; **OR**
 - Adenocarcinoma of duodenum or ampulla; **OR**
 - Stromal/neuroendocrine tumor of the esophagus, stomach, or duodenum; **OR**
 - Other subepithelial pre-malignant lesion of the esophagus, stomach, or duodenum; **OR**
 - Adenomatous polyp of stomach, duodenum, or ampulla; **OR**
 - Dysplasia (low or high grade) in patients with gastric intestinal metaplasia or chronic atrophic gastritis; **OR**
- ◆ Confirmed or suspected eosinophilic esophagitis (EoE) for **ANY** of the following³²:
 - Initial exam for suspected EoE for evaluation of dysphagia, GERD symptoms refractory to PPI therapy, or history of esophageal food bolus impaction; **OR**
 - Follow-up exam to reassess esophageal histology for confirmed EoE, after treatment (e.g., food allergen restriction, PPI therapy, steroid therapy, anti-interleukin therapy); **OR**
 - Follow-up exam to reassess esophagus when symptoms recur on previously effective therapy; **OR**
- ◆ Evaluation of chronic diarrhea to identify an upper GI etiology (e.g., celiac disease) when small bowel disease is suspected; **OR**
- ◆ Suspected celiac disease based on **ANY** of the following³³:

- Typical signs or symptoms (e.g., abdominal pain, diarrhea, constipation, weight loss without intent, iron deficiency anemia); **OR**
- Abnormal celiac serology including **ANY** of the following:
 - Elevated tissue transglutaminase immunoglobulin A (TTG IgA) with normal total IgA; **OR**
 - Elevated endomysial IgA with normal total IgA; **OR**
 - Elevated deamidated anti-gliadin IgG with IgA deficiency; **OR**
- The patient is at a high-risk based on celiac human leucocyte antigen (HLA) analysis; **OR**
- ◆ Known celiac disease with **ANY** of the following³³:
 - The patient has been on a gluten-free diet for at least 1 year and requires histologic confirmation of remission; **OR**
 - Symptoms persist despite adherence to a gluten-free diet for at least 6 months; **OR**
- ◆ Acute injury including, but not limited to, **ANY** of the following:
 - Caustic agent ingested; **OR**
 - Sharp foreign object ingested³⁴; **OR**
- ◆ Evaluation for esophagogastric varices (swollen veins [varices] in the esophageal or gastric wall) due to suspicion for or confirmation of liver cirrhosis or portal hypertension³⁵; **OR**
- ◆ Routine surveillance of non-bleeding esophagogastric varices per established guidelines every 3 years³⁵⁻³⁶; **OR**
- ◆ Evaluation of GI bleeding and **ANY** of the following:
 - Upper GI symptoms; **OR**
 - Melena (dark stool); **OR**
 - Presumed chronic blood loss (iron deficiency anemia, positive fecal occult blood test, or both) when colonoscopy is negative³⁷; **OR**
 - Active bleeding is present (hematemesis, melena, or hematochezia); **OR**
 - Recent active bleeding (within 72 hrs) and etiology remain unknown; **OR**
 - Suspected aorto-enteric fistula; **OR**

- Re-bleeding occurs after recent endoscopic therapy; **OR**
- Surgery is being considered; **OR**
- ◆ Suspected inflammation of the upper gastrointestinal (GI) tract from etiologies including, but not limited to, inflammatory myositis, Crohn's disease, ulcerative colitis, inflammatory bowel disease (IBD), and acute graft versus host disease³⁸⁻³⁹; **OR**
- ◆ Conditions in which upper GI pathology might modify other planned management, such as patients with **ANY** of the following⁹:
 - Organ transplantation is planned; **OR**
 - Long-term anticoagulation therapy; **OR**
 - Long-term nonsteroidal anti-inflammatory drug therapy for arthritis; **OR**
 - Cancer of the head and neck; **OR**
 - Bariatric surgery is planned.⁴⁰

Non-Indications

→ **Diagnostic esophagogastroduodenoscopy (EGD)** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Blockage in the esophagus, stomach, or duodenum is previously established; **OR**
- ◆ Surveillance of healed, benign disease, such as gastric or duodenal ulcer or benign esophageal strictures¹; **OR**
- ◆ Confirming *Helicobacter pylori* eradication; **OR**
- ◆ Cancer surveillance in patients with pernicious anemia, treated achalasia, or prior gastric resection¹; **OR**
- ◆ Patients with cardiac arrhythmia or recent myocardial infarction¹; **OR**
- ◆ Perforated bowel; **OR**
- ◆ Peritonitis; **OR**
- ◆ Toxic megacolon in an unstable patient; **OR**
- ◆ Perforated viscus is known or suspected; **OR**
- ◆ Before bariatric surgery in asymptomatic individuals; **OR**
- ◆ Confirming placement of gastric band; **OR**

◆ Diagnosing laryngopharyngeal reflux.

*Note: Patients undergoing dilations, percutaneous endoscopic gastrostomy [PEG], polypectomy, endoscopic sphincterotomy, endoscopic ultrasound-guided fine-needle aspiration [FNA], laser ablation, and coagulation are at higher risk for bleeding, and adjustment of anticoagulation may be necessary.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)

43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis.

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Gyawali et al. (2020) recommend the use of ambulatory reflux monitoring over the assessment of response to proton pump inhibitor (PPI) therapy for a conclusive diagnosis of gastroesophageal reflux disease (GERD) in patients with esophageal reflux symptoms. The increasing popularity of PPI trials for suspected GERD symptoms has decreased the likelihood of finding reflux esophagitis using EGD. In this study, among 696 patients undergoing EGD for suspected GERD symptoms, those without reflux esophagitis were more likely to be on PPI therapy than those with erosive esophagitis (53% versus 29%, $P < 0.001$). Among over 700 patients with a partial response to PPI therapy, only 20% to 30% had esophageal mucosal breaks on EGD. Therefore, despite high specificity, EGD has low sensitivity when diagnosing GERD. However, the authors note high-quality EGD is essential before further evaluating esophageal symptoms.⁴¹

Schuldt et al. (2019) evaluated the demand for nasal EGD with ultrathin endoscopes as an alternative to diagnostic peroral EGD. Nasal EGD has been considered to reduce patients' discomfort and anxiety and avoid sedation-related adverse effects. In the study, among outpatients with no contraindications for nasal EGD, 60% chose nasal EGD, underscoring an existing demand for nasal EGD in outpatients. Of the 196 patients eligible for the study, 77% had previously undergone peroral EGD. Of the patients who underwent nasal EGD, 83% were fairly to extremely satisfied with the procedure. Patients who chose a specific procedure (peroral or nasal EGD) were more likely to select the same procedure as their future preference. This preference was unaffected by the procedure that patients chose previously.¹²

Mazzeffi et al. (2021) evaluated the efficacy of high-flow nasal cannula (HFNC) oxygen in reducing the incidence of hypoxemia during anesthesia for

advanced EGD. In a randomized controlled trial (RCT) that included 262 adult patients undergoing anesthesia for advanced EGD, HFNC oxygen significantly reduced the incidence of one or more hypoxemia events from 33.1% to 21.2%.⁴²

Sengupta et al. (2024) documented the recommendations of a panel of experts from the American College of Gastroenterology and the Society of Abdominal Radiology, including comparing the advantages and limitations of endoscopic versus radiologic diagnostic examinations in patients with gastrointestinal bleeding. The authors note that unless contraindicated, the evaluation of non-variceal upper gastrointestinal bleeding begins with EGD, with the ideal timing for the procedure being within 24 hours of presentation, with high mortality seen when performed early (less than 6–12 hours) or later (greater than 24–36 hours).⁴³

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Clinical Guideline Revision History/Information

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Review History		

Cohere Medical Policy – Esophagogastroduodenoscopy (EGD)

Clinical Policy for Medical Necessity Review

CHP-027-3 Version 3

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Specialty: Gastroenterology

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Procedure Codes (CPT/HCPCS)

Service: Esophagogastroduodenoscopy (EGD)	
Code	Description
43191	Esophagoscopy, rigid, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed (separate procedure)
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
43193	Esophagoscopy, rigid, transoral; with biopsy, single or multiple
43194	Esophagoscopy, rigid, transoral; with removal of foreign body(s)
43195	Esophagoscopy, rigid, transoral; with balloon dilation (less than 30 mm diameter)
43196	Esophagoscopy, rigid, transoral; with insertion of guide wire followed by dilation over guide wire
43197	Esophagoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43198	Esophagoscopy, flexible, transnasal; with biopsy, single or multiple
43200	Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43202	Esophagoscopy, flexible, transoral; with biopsy, single or multiple
43226	Esophagoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) over guide wire
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43240	Esophagogastroduodenoscopy, flexible, transoral; with transmural drainage of pseudocyst (includes placement of transmural drainage catheter[s]/stent[s], when performed, and endoscopic ultrasound, when performed)
43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter

43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43243	Esophagogastroduodenoscopy, flexible, transoral; with injection sclerosis of esophageal/gastric varices
43244	Esophagogastroduodenoscopy, flexible, transoral; with band ligation of esophageal/gastric varices
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (eg, balloon, bougie)
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body(s)
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire
43249	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)
43250	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method
43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])
43499	Unlisted procedure, esophagus
43999	Unlisted procedure, stomach

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Service: Esophagogastroduodenoscopy (EGD) - Description

Esophagogastroduodenoscopy (EGD) is an endoscopic procedure that allows direct visualization of the esophagus, stomach, and duodenum using a flexible endoscope. It is performed for diagnostic and therapeutic purposes, using a thin, flexible tube with a light and camera to observe anatomy, biopsy may be taken, performed under sedation, etc.

Service: Esophagogastroduodenoscopy (EGD) - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Indications

- An **esophagogastroduodenoscopy (EGD)** is considered appropriate if **ANY** of the following is **TRUE**:
 - Gastroesophageal reflux disease (GERD), known or suspected, for **ANY** of the following¹:
 - One-time screening exam for GERD with **AT LEAST THREE** of the following risk factors for concurrent Barrett's esophagus²⁻⁵:
 - Greater than 50 years of age; **OR**
 - Alarm symptoms^A; **OR**
 - Current or past tobacco use; **OR**
 - Family history of a first-degree relative with **ANY** of the following, regardless of the patient's symptomology:
 - ▲ Barrett's esophagus; **OR**
 - ▲ Esophageal adenocarcinoma; **OR**
 - Hiatal hernia^{2,6}; **OR**
 - Male gender; **OR**
 - Obesity (body mass index [BMI] greater than or equal to 30kg/m²); **OR**
 - White race; **OR**
 - Previous diagnosis of grade C or D reflux esophagitis and follow up EGD to evaluate **ANY** of the following:
 - Healing; **OR**

- ☐ Absence of Barrett's esophagus after reflux treatment^B; **OR**
- Greater than or equal to 3 years since sleeve gastrectomy, without GERD symptoms; **OR**
- GERD symptoms with **ANY** of the following^{B,3,7}:
 - ☐ Symptoms persist following sleeve gastrectomy; **OR**
 - ☐ Symptoms persist despite treatment with H2 receptor antagonist, proton pump inhibitor (PPI), or potassium-competitive acid blockers (PCAB) medication for greater than or equal to 8 weeks; **OR**
 - ☐ Placement of a wireless esophageal pH monitoring device; **OR**
 - ☐ Prior peroral endoscopic myotomy (POEM) for treatment of achalasia; **OR**
 - ☐ Recurrence after discontinuation of a successful treatment course for greater than or equal to 8 weeks; **OR**
- Post-operative evaluation following anti-reflux surgery with **ANY** of the following:
 - ☐ Dysphagia; **OR**
 - ☐ Recurrent typical reflux symptoms; **OR**
- Pre-operative evaluation for anti-reflux surgery with **ANY** of the following:
 - ☐ EGD not performed within the last 12 months; **OR**
 - ☐ EGD performed within the last 12 months with new alarm symptoms^A, or if prior exam had findings that require follow-up (e.g., grade C/D esophagitis); **OR**
- Suspected GERD with extraesophageal symptoms^C with **ANY** of the following:
 - ☐ Accompanied by typical GERD symptoms^B with failure of a trial of twice-daily PPI therapy for greater than or equal to 8 weeks; **OR**
 - ☐ Not accompanied by typical GERD symptoms^B with **ANY** of the following:
 - ▲ Evaluation and exclusion of other causes by an allergy, otolaryngology (ear, nose, throat [ENT]), or pulmonology consultation; **OR**
 - ▲ Failure of a trial of twice-daily PPI therapy for greater than or equal to 8 weeks; **OR**
- Upper abdominal distress^D and **ANY** of the following⁸:
 - Greater than or equal to 60 years of age; **OR**
 - Less than or equal to 60 years of age with **ANY** of the following:
 - ☐ Alarm symptoms^A with or without a family history of upper gastrointestinal (GI) cancer in a first-degree relative; **OR**
 - ☐ Non-invasive test for *Helicobacter pylori* (*H. pylori*)^E with equivocal result and there is a need for gastric biopsy^{9,10}; **OR**
 - ☐ Negative *H. pylori* test^E with inadequate response to **ANY** of the following^{7,8,10}:
 - ▲ PPI or PCAB therapy for greater than or equal to 4 weeks; **OR**
 - ▲ Prokinetic therapy^F for greater than or equal to 4 weeks; **OR**
 - ▲ Tricyclic antidepressant (TCA) therapy^G for greater than or equal to 6 weeks; **OR**
 - ☐ Palpable abdominal mass; **OR**
 - ☐ Positive *H. pylori* test^E with persistent symptoms for greater than or equal to 4 weeks after completion of treatment; **OR**
 - ☐ Positive *H. pylori* test^E with persistent symptoms after subsequent breath or stool testing that confirms eradication of infection; **OR**
 - ☐ Presence of lymphadenopathy (e.g., supraclavicular, periumbilical, etc.); **OR**
- Barrett's esophagus surveillance for known/established intestinal metaplasia or columnar epithelium with goblet cells in the tubular esophagus in **ANY** of the following scenarios:
 - Barrett's segment less than 3 cm in length with no dysplasia, at 5 years from prior EGD; **OR**
 - Barrett's segment greater than or equal to 3 cm in length with no dysplasia, at 3 years from prior EGD; **OR**

- Barrett's segment of any length with **ANY** of the following:
 - Indefinite dysplasia with **ANY** of the following:
 - ▲ First surveillance EGD within 6 months of original diagnosis and PPI therapy has been increased to twice-daily; **OR**
 - ▲ If stable on first surveillance (i.e., indefinite dysplasia or no dysplasia, but no progression to low-grade dysplasia, high-grade dysplasia, or cancer), then EGD once yearly; **OR**
 - ▲ If regression observed (no dysplasia) on any yearly surveillance EGD exam, then EGD every 3-5 years; **OR**
 - Low-grade dysplasia with **ALL** of the following:
 - ▲ The patient elects against endoscopic elimination therapy (EET)^H; **AND**
 - ▲ **ANY** of the following:
 - △ First surveillance EGD can be performed within 6 months of original diagnosis and PPI therapy has been increased to twice-daily; **OR**
 - △ If stable on first surveillance (i.e., low grade dysplasia, indefinite dysplasia, or no dysplasia, but no progression to high grade dysplasia or cancer), then EGD once yearly; **OR**
 - △ If no dysplasia on 2 consecutive surveillance EGD exams, then EGD every 3 years; **OR**
 - High-grade dysplasia with **ALL** of the following:
 - ▲ The patient elects against EET^H; **AND**
 - ▲ **ANY** of the following:
 - △ Surveillance EGD can be performed every 3 months for 1 year and PPI therapy has been increased to twice a day; **OR**
 - △ If stable over 1 year (i.e., high grade dysplasia, low grade dysplasia, indefinite dysplasia, or no dysplasia, but no progression to cancer), then EGD every 6 months for 1 year; **OR**
 - △ If stable for the next year following 1 year of stability (i.e., high grade dysplasia, low grade dysplasia, indefinite dysplasia, or no dysplasia, but no progression to cancer), then EGD once yearly; **OR**
- Surveillance after prior EET^H with **ALL** of the following:
 - **ANY** of the following procedures:
 - ▲ Radiofrequency ablation (RFA); **OR**
 - ▲ Cryoablation; **OR**
 - ▲ Endoscopic mucosal resection (EMR); **OR**
 - ▲ Endoscopic submucosal dissection (ESD); **AND**
 - **ANY** of the following:
 - ▲ EGD as frequently as every 3 months while undergoing EET^H in order to achieve complete elimination of Barrett's/intestinal metaplasia (CEIM); **OR**
 - ▲ No dysplasia at baseline before treatment, then EGD every 3-5 years after achieving CEIM; **OR**
 - ▲ Low-grade dysplasia at baseline before treatment, and **ANY** of the following intervals:
 - △ EGD at 1 year after achieving CEIM, if stable; **OR**
 - △ EGD every 2 years thereafter; **OR**
 - ▲ High-grade dysplasia or stage T1a esophageal adenocarcinoma at baseline before treatment, and **ANY** of the following intervals¹¹:
 - △ EGDs every 3 months up to 12 months after achieving CEIM, if stable; **OR**
 - △ After the first year, EGD once every year; **OR**
- History of caustic ingestion with **ANY** of the following^{12,13}:
 - Assess mucosal injury; **OR**

- Surveillance of esophageal cancer (at 10 years after initial diagnosis of caustic ingestion, then every 2 years)¹¹; **OR**
- Atypical chest pain that is presumed secondary to GERD with **ANY** of the following⁷:
 - Typical GERD symptoms^B; **OR**
 - No typical GERD symptoms after cardiac disease has been ruled out⁸; **OR**
- Celiac disease for **ANY** of the following:
 - Established celiac disease with **ANY** of the following^{14,15}:
 - Asymptomatic with gluten-free diet for at least 2 years, for histologic confirmation of duodenal mucosal healing; **OR**
 - Symptoms persist despite adherence to a gluten-free diet for at least 6 months; **OR**
 - Suspected celiac disease on the basis of symptoms, signs, or laboratory evidence¹ with **ANY** of the following^{14,15}:
 - Abnormally elevated celiac serology, including **ANY** of the following:
 - ▲ Deamidated immunoglobulin G (IgG) anti-gliadin Ab; **OR**
 - ▲ IgA tissue transglutaminase (anti-tTG) Ab; **OR**
 - ▲ IgA anti-endomysial Ab; **OR**
 - ▲ IgA anti-gliadin Ab; **OR**
 - Any alarm sign or symptom^A; **OR**
 - High-risk for celiac disease based on high likelihood result from analysis of celiac-associated human leucocyte antigen (HLA-DQ2 or HLA-DQ8); **OR**
 - Negative celiac serologic screening test with **ANY** of the following:
 - ▲ Coexistence of other autoimmune disease; **OR**
 - ▲ High clinical suspicion for celiac disease¹; **OR**
 - Positive celiac serologic screening test with a first-degree family member who has a confirmed diagnosis of celiac disease (with or without symptoms); **OR**
- Clarification of location or pathology of a lesion to guide surgery¹⁶; **OR**
- Conditions in which upper GI pathology might modify other planned management, including **ANY** of the following^{3,12}:
 - Bariatric surgery is scheduled¹⁷; **OR**
 - Cancer of the head or neck; **OR**
 - History of ulcer disease or GI bleeding when organ transplantation is scheduled; **OR**
 - Long-term anticoagulation therapy; **OR**
 - Long-term nonsteroidal anti-inflammatory drug therapy for arthritis; **OR**
- Confirmation and specific histologic diagnosis of radiologically demonstrated lesions, including **ANY** of the following¹⁸⁻²¹:
 - A lesion that requires biopsy for diagnosis; **OR**
 - Excavated lesions (e.g., erosions, ulcers, diverticula)¹²; **OR**
 - Other mucosal abnormalities^J; **OR**
 - Protrusions/growths from, within, or extrinsic to the mucosal wall; **OR**
 - Suspected neoplastic lesion; **OR**
 - Upper GI tract stricture or obstruction; **OR**
- Eosinophilic esophagitis (EoE) (confirmed or suspected) for **ANY** of the following^{22,23}:
 - Initial examination for suspected EoE for evaluation of **ANY** of the following:
 - After removal of esophageal food bolus, if suspected and confirmatory biopsies not taken at time of bolus removal; **OR**

- ☐ Dysphagia; **OR**
- ☐ GERD symptoms refractory to PPI therapy; **OR**
- Histologically confirmed EoE from a prior exam to follow-up mucosal and histological appearance of the esophagus after **ANY** of the following^K:
 - ☐ Food reintroduction protocol for greater than or equal to 8 weeks to identify clear disease triggers; **OR**
 - ☐ Treatment with PPI or PCAB for greater than or equal to 8 weeks; **OR**
 - ☐ Treatment has been instituted or augmented by **ANY** of the following:
 - ▲ Advanced therapy (dupilumab) for greater than or equal to 8 weeks; **OR**
 - ▲ Selective food elimination protocol for greater than or equal to 8 weeks; **OR**
 - ▲ Topical steroids (budesonide or fluticasone) for greater than or equal to 8 weeks; **OR**
- To facilitate therapeutic dilation of persistent or recurrent dysphagia related to disease-associated esophageal stricture, if present after medical therapy; **OR**
- Esophageal dysmotility based on barium radiography or esophageal manometry when suggestive of achalasia^{L,18}; **OR**
- Evaluation for **ANY** of the following:
 - To identify an upper GI etiology (e.g., celiac disease) when **ALL** of the following:
 - ☐ Chronic diarrhea; **AND**
 - ☐ Non-diagnostic results from cross-sectional imaging, stool testing, and/or diagnostic colonoscopy with random biopsy; **OR**
 - GI bleeding and **ANY** of the following:
 - ☐ Acute upper GI bleeding (i.e., active, recent, recurrent) that presents with **ANY** of the following:
 - ▲ Hematemesis; **OR**
 - ▲ Hematochezia; **OR**
 - ▲ Melena; **OR**
 - ☐ Presumed chronic GI blood loss^M when colonoscopy is negative and **ANY** of the following are present²⁴:
 - ▲ Iron deficiency anemia^M with **ANY** of the following:
 - △ Elevated serum iron binding capacity; **OR**
 - △ Low serum ferritin; **OR**
 - △ Low serum iron; **OR**
 - △ Low serum transferrin saturation; **OR**
 - ▲ Positive fecal occult blood test (e.g., guaiac, fecal immunochemical test [FIT]) when clinical situation suggests an upper GI bleeding source (e.g., upper GI symptoms present); **OR**
 - ▲ Iron deficiency anemia without preceding colonoscopy if plan is for EGD and colonoscopy simultaneously²⁵; **OR**
 - ☐ Re-bleeding occurs after recent endoscopic therapy^N; **OR**
 - ☐ Surgery is being considered; **OR**
 - ☐ Suspected aorto-enteric fistula; **OR**
 - ☐ Upper GI symptoms; **OR**
 - Intraoperative evaluation of anatomic reconstruction of modern foregut surgery^O; **OR**
 - Possible gastric or duodenal polyps in patients with familial adenomatous polyposis or other at-risk hereditary syndromes^{P,12,26-28}; **OR**
 - Swallowing symptoms, including **ANY** of the following:
 - ☐ Dysphagia; **OR**

- ☐ Odynophagia; **OR**
- Repeat or periodic/serial EGD when index EGD demonstrates **ANY** of the following:
 - ☐ Los Angeles (LA) grade C or D erosive esophagitis as the cause of swallowing symptoms, to document healing and absence of Barrett's esophagus; **OR**
 - ☐ Severely narrowed esophageal stricture or stenosis that is amenable to serial bougie or balloon dilation; **OR**
- Monitoring of gastric pre-malignant conditions, including **ANY** of the following:
 - After resection of visible/raised dysplasia/adenoma (any grade), to survey the resection site(s) at **ANY** of the following intervals:
 - ☐ Low-grade dysplasia resected with clear margins, EGD in 1 year, then every 3 years if stable (e.g., no recurrence); **OR**
 - ☐ Low-grade dysplasia resected with involved margins, EGD every 6 months until clear of dysplasia from further resection/ablation or until surgical resection is advised; **OR**
 - ☐ High-grade dysplasia resected with clear margins, EGD every 3-6 months for 2 years, then every 3 years if stable (e.g., no recurrence); **OR**
 - ☐ High-grade dysplasia resected with involved margins, EGD every 1-3 months until clear of dysplasia from further resection/ablation or until surgical resection is advised; **OR**
 - Follow-up of gastric intestinal metaplasia every 3 years after histologically confirmed diagnosis for **ANY** of the following:
 - ☐ Any variant of gastric intestinal metaplasia histology with **ANY** of the following²⁹:
 - ▲ Family history of gastric cancer in a first-degree relative; **OR**
 - ▲ Foreign-born and immigrated from a high-incidence nation^Q; **OR**
 - ▲ High-risk race or ethnicity^R; **OR**
 - ☐ High-risk gastric intestinal metaplasia histology in the form of **ANY** of the following:
 - ▲ Incomplete gastric intestinal metaplasia; **OR**
 - ▲ Involvement of the gastric corpus (body) on prior sampling; **OR**
 - Hyperplastic gastric polyps greater than 10 mm, after selective resection with treatment of *H. pylori* (if found on biopsy of surrounding mucosa), **ANY** of the following intervals:
 - ☐ One-time at 1 year if no dysplasia found; **OR**
 - ☐ Every 1 year if dysplasia found; **OR**
 - When a gastric biopsy is needed to diagnose a possible *H. pylori* infection, and results from prior non-invasive testing^E are equivocal/indefinite; **OR**
 - Non-visible/flat dysplasia/adenoma to survey for change with biopsy with **ANY** of the following:
 - ☐ High grade, every 3 months; **OR**
 - ☐ Indefinite or low grade, every 6-12 months; **OR**
 - Severe gastric intestinal metaplasia or atrophic gastritis involving the corpus (body) or antrum (every 3 years); **OR**
 - Visible/raised dysplasia/adenoma (e.g., indefinite, low grade, or high grade) to facilitate **ANY** of the following:
 - ☐ Endoscopic mucosal resection; **OR**
 - ☐ Submucosal dissection; **OR**
- Pediatric patient with **ANY** of the following:
 - Abdominal pain with suspicion of an organic disease³⁰; **OR**
 - Anemia, unexplained³⁰; **OR**
 - Caustic ingestion^{12,13,30}; **OR**
 - Chronic diarrhea, unexplained³⁰; **OR**

- Dysphagia or odynophagia^{12,30}; **OR**
- Esophagitis (eosinophilic or infectious)³¹; **OR**
- GERD (chronic) to exclude other diseases^{30,31}; **OR**
- Hematemesis^{30,31}; **OR**
- Hematochezia³⁰; **OR**
- Surveillance of Barrett's esophagus^{12,30,31}; **OR**
- Suspicion of graft versus host disease^{30,32,33}; **OR**
- Vomiting that is recurrent with unknown cause³⁰; **OR**
- Weight loss or failure to thrive^{S,30}; **OR**
- Peptic ulcer disease after diagnosis of esophageal, gastric, duodenal, or stomal ulcer disease with **ANY** of the following^{1,34,35}:
 - Ulcer was uncomplicated^T with symptoms (e.g., persistent or recurrent) despite treatment; **OR**
 - Documentation of healing for a complicated ulcer after at least 2 months, then every 2-4 months thereafter until healing is confirmed; **OR**
 - Diagnosed ulcer deemed suspicious for malignancy with inconclusive histology for **ANY** of the following:
 - Dysplasia; **OR**
 - Malignancy; **OR**
- Sampling of **ANY** of the following to obtain tissue or fluid from:
 - Duodenum; **OR**
 - Jejunum; **OR**
- Surveillance for suspected recurrence of prior upper GI cancer or pre-cancer, including **ANY** of the following³⁴:
 - **ANY** of the following adenocarcinomas³⁶:
 - Duodenum or ampulla; **OR**
 - Esophagus; **OR**
 - Stomach^{33,37}; **OR**
 - Adenomatous polyp of **ANY** of the following:
 - Ampulla; **OR**
 - Duodenum, including **ANY** of the following:
 - ▲ Ampullary (EGD 3 months after resection, then 6 months after resection, then 12 months after resection, and if no recurrence, then every 1 year for 5 years); **OR**
 - ▲ Non-ampullary (EGD every 3-6 months until complete resection confirmed, then EGD in 1 year); **OR**
 - Stomach; **OR**
 - Dysplasia (low or high grade) in patients with gastric intestinal metaplasia or chronic atrophic gastritis¹²; **OR**
 - Gastrointestinal stromal tumor (GIST) of the esophagus, stomach, or duodenum and **ALL** of the following³⁸:
 - EGD (with or without US) every 1 year; **AND**
 - Tumor is **ANY** of the following:
 - ▲ Less than 2 cm; **OR**
 - ▲ Greater than 2 cm, and surgical resection is not elected; **OR**
 - Mucosa-associated lymphoma (MALT) of the stomach; **OR**
 - Neuroendocrine tumor and **ALL** of the following:

- ☐ EGD every 6-12 months for 3 years, then once yearly; **AND**
- ☐ Neuroendocrine tumor in the duodenum, esophagus, or stomach; **OR**
- Squamous cell carcinoma of the esophagus³⁹; **OR**
- Surveillance of portal hypertension and esophagogastric varices with **ANY** of the following^{40,41}:
 - Intolerance or contraindication to non-selective beta-blocker therapy with **ANY** of the following:
 - ☐ Decompensated cirrhosis^U and **ANY** of the following intervals:
 - ▲ EGD at the time of decompensation for patients with previously compensated cirrhosis; **OR**
 - ▲ Follow up every 1 year if no prior bleeding from varices in a patient; **OR**
 - ☐ Initial screening for varices in a patient with compensated cirrhosis and clinically significant portal hypertension (CSPH), defined as **ANY** of the following:
 - ▲ Disease progression to liver decompensation; **OR**
 - ▲ Hepato-portal venous gradient (HPVG) greater than or equal to 10 mmHg; **OR**
 - ▲ Liver stiffness measurement (LSM) on transient elastography greater than or equal to 25 kPa, irrespective of platelet count; **OR**
 - ▲ LSM 20–24.9 kPa with platelet count less than 150 K/mm³; **OR**
 - ▲ LSM 15–19.9 kPa with platelet count less than 110 K/mm³; **OR**
 - ▲ Portosystemic collaterals or hepatofugal flow on imaging; **OR**
 - ☐ Follow-up for progression every 2-3 years in a patient with **ALL** of the following:
 - ▲ Absence of varices; **AND**
 - ▲ Compensated cirrhosis; **AND**
 - ▲ CSPH; **OR**
 - ☐ Follow-up for progression every 1-2 years in a patient with **ALL** of the following:
 - ▲ Compensated cirrhosis; **AND**
 - ▲ CSPH; **AND**
 - ▲ Known non-bleeding varices or ongoing alcohol consumption; **OR**
 - ☐ To facilitate esophageal variceal band ligation (EVL) every 2–4 weeks until obliteration in a patient with **ALL** of the following:
 - ▲ Compensated cirrhosis; **AND**
 - ▲ CSPH; **AND**
 - ▲ High risk varices (grade 3 or 4); **AND**
 - ▲ After initial band ligation for previous variceal bleeding (secondary prophylaxis) or after initial band ligation to prevent bleeding from high-risk varices (primary prophylaxis) with **ANY** of the following:
 - △ Every 2-4 weeks until obliteration is achieved; **OR**
 - △ At 6 months after obliteration is achieved; **OR**
 - △ At 12 months after obliteration is achieved; **OR**
 - △ Every 12 months thereafter; **OR**
- Suspected inflammation of the upper gastrointestinal (GI) tract from etiologies including **ANY** of the following^{32,33}:
 - Acute graft versus host disease^{32,33}; **OR**
 - Crohn's disease with **ANY** of the following:
 - ☐ Established, when upper GI tract symptoms are present; **OR**
 - ☐ Suspected, upper GI tract symptoms are present with colonoscopy that is non-diagnostic or negative; **OR**

- Inflammatory myositis (dermatomyositis or polymyositis); **OR**
- Therapeutic treatment of **ANY** of the following:
 - Acutely bleeding, non-variceal lesions^V with endoscopic therapy^N; **OR**
 - Acutely bleeding esophagogastric varices using **ANY** of the following:
 - ☐ Band ligation; **OR**
 - ☐ Balloon tamponade; **OR**
 - ☐ Sclerotherapy; **OR**
 - ☐ Stent tamponade; **OR**
 - Endoscopic ablation therapy of Barrett's esophagus with low or high-grade dysplasia; **OR**
 - Feeding tube placement or removal (e.g., oral, percutaneous endoscopic gastrostomy, percutaneous endoscopic jejunostomy); **OR**
 - Localization of a lesion (including tattoo marking) before or during surgery; **OR**
 - Management of benign stenotic lesions with **ANY** of the following:
 - ☐ Balloon dilators; **OR**
 - ☐ Electric knife stricturotomy; **OR**
 - ☐ Stent placement; **OR**
 - ☐ Wire-guided bougies; **OR**
 - Non-surgical management of diagnostically-proven achalasia^W; **OR**
 - Management of diverticular lesions (e.g., endoscopic myotomy); **OR**
 - Palliative therapy of stenosing neoplasms (e.g., stent placement, electrocoagulation); **OR**
 - Re-investigation and re-treatment of recurrent upper GI bleeding after recent (within 72 hours) endoscopic therapy^N; **OR**
 - Removal of foreign bodies, including food bolus impaction^{12,42}; **OR**
 - Removal of selected polypoid lesions with **ANY** of the following:
 - ☐ EMR; **OR**
 - ☐ ESD; **OR**
 - ☐ Polypectomy; **OR**
 - Management of operative complications^X, including **ANY** of the following:
 - ☐ Stent placement of anastomotic disruption/fistula/leak; **OR**
 - ☐ Symptoms from anastomotic strictures requiring dilation; **OR**
 - ☐ Symptoms suggesting complications of bariatric surgery, including **ANY** of the following:
 - ▲ Abdominal pain; **OR**
 - ▲ Bleeding or anemia; **OR**
 - ▲ Diarrhea/dumping syndrome; **OR**
 - ▲ Failure to lose weight as anticipated; **OR**
 - ▲ Nausea or vomiting; **OR**
 - ▲ New onset GERD after surgery; **OR**
 - ▲ Unexplained weight loss^S, or anorexia⁷; **OR**
- Upper GI tract screening or surveillance for possible esophageal or gastroduodenal polyps or cancer in patients with **ANY** of the following:
 - Family history of gastric cancer, as a one-time screening; **OR**
 - Familial adenomatous polyposis (FAP), attenuated familial adenomatous polyposis (AFAP), or MUTYH-associated polyposis (MAP) for **ANY** of the following^{27,28}:

- ☐ As an initial screening starting at age 25; **OR**
- ☐ As a surveillance for **ANY** of the following:
 - ▲ Every 3-5 years if no evidence of gastric, duodenal, or periampullary adenoma/dysplasia; **OR**
 - ▲ Every 2-3 years for small or isolated adenomatous polyps, or low-grade dysplasia in gastric adenoma(s) or dysplasia that is completely resected endoscopically; **OR**
 - ▲ Every 1 year for proximal gastric location or more extensive adenomatous polyp involvement; **OR**
 - ▲ Every 3-6 months for large adenomatous polyps, or high-grade dysplasia, or other high-risk histology in gastric adenoma(s); **OR**
 - ▲ For duodenal or periampullary adenoma/dysplasia that is resected endoscopically, then according to Spigelman criteria, with **ANY** of the following:
 - △ Stage I, every 2–3 years; **OR**
 - △ Stage II, every 1–2 years; **OR**
 - △ Stage III, every 6–12 months; **OR**
 - △ Stage IV, every 3–6 months (if surgery is not elected); **OR**
- Other at-risk hereditary syndromes, including **ANY** of the following:
 - ☐ Cowden (PTEN hamartoma tumor) syndrome (initially age 15, every 2-3 years); **OR**
 - ☐ Hereditary gastric cancer syndrome (initially at diagnosis of CDH1 gene mutation; if prophylactic gastrectomy is not chosen, then surveillance EGD every 6 months); **OR**
 - ☐ Juvenile polyposis syndrome (initially at age 12-15, every 2-3 years if no polyps, or every year if polyps removed); **OR**
 - ☐ Li-Fraumeni syndrome if associated with family history of gastric cancer (initially at age 25, every 2-3 years); **OR**
 - ☐ Lynch syndrome (initially at age 30-40, every 2-4 years); **OR**
 - ☐ Peutz-Jegher's syndrome (initially at age 18, every 2-3 years); **OR**
 - ☐ Tylosis (palmo-plantar keratoderma esophageal cancer syndrome), initially at age 30 or at diagnosis, then every 1 year; **OR**
- Vomiting that is persistent and unexplained^{7,12}; **OR**
- EGD with endoscopic ultrasound (EUS) for **ANY** of the following diagnostic indications⁴³:
 - Evaluation of **ANY** of the following:
 - ☐ Abnormalities within the GI tract wall^Y; **OR**
 - ☐ Abnormalities of organs adjacent to the GI tract^Y; **OR**
 - ☐ Biliary tree for **ANY** of the following^{44,45}:
 - ▲ Characterization and possible tissue sampling of abnormalities of the biliary tree with **ANY** of the following:
 - △ Endoscopic retrograde cholangiopancreatography (ERCP); **OR**
 - △ ERCP is contraindicated; **OR**
 - ▲ Initial ultrasound, computed tomography (CT) scan, or magnetic resonance imaging (MRI) is nondiagnostic or inconclusive, and clinical suspicion remains high for **ANY** of the following known or suspected conditions:
 - △ Biliary stricture or obstruction⁴⁶; **OR**
 - △ Choledocholithiasis; **OR**
 - △ Cholelithiasis; **OR**
 - △ Structural or congenital abnormality; **OR**
 - ☐ Other abdominal or pelvic abnormalities when diagnostic imaging is insufficient or indeterminate; **OR**

- Pancreas for **ANY** of the following:
 - ▲ Characterization and possible tissue sampling of **ANY** of the following:
 - △ Abnormalities when detected on prior imaging, including **ANY** of the following:
 - ◆ Indeterminate cysts; **OR**
 - ◆ Masses; **OR**
 - ◆ Pancreatic ductal dilation in order to exclude obstructive lesion or intraductal mucinous tumor; **OR**
 - ◆ Pseudocysts^{44,47}; **OR**
 - ◆ Tissue prominence or fullness; **OR**
 - △ Etiologies for unexplained acute or recurrent pancreatitis when diagnostic imaging is inconclusive⁴⁴; **OR**
 - ▲ Confirmation of **ANY** of the following when diagnostic imaging is inconclusive:
 - △ Suspected autoimmune pancreatitis; **OR**
 - △ Suspected chronic pancreatitis as a possible etiology for chronic unexplained upper abdominal pain; **OR**
 - ▲ Screening for pancreatic cancer with **ANY** of the following⁴⁸:
 - △ Family history of pancreatic cancer, including **ANY** of the following:
 - ◆ Two or more first-degree relatives; **OR**
 - ◆ Three or more affected relatives on the same side of the family, when at least one is a first-degree relative; **OR**
 - △ Increased risk of pancreatic cancer from **ANY** of the following hereditary risk scenarios:
 - ◆ Presence of a germline mutation regardless of family history in **ANY** of the following:
 - ◇ CDKN2A (familial atypical multiple mole melanoma syndrome); **OR**
 - ◇ PRSS1 (hereditary pancreatitis); **OR**
 - ◇ STK11 (Peutz-Jeghers syndrome); **OR**
 - ◆ Presence of a germline mutation with a family history of pancreatic cancer in a first-degree relative in **ANY** of the following:
 - ◇ ATM; **OR**
 - ◇ BRCA2; **OR**
 - ◇ Lynch Syndrome mutation (e.g., MLH1, MSH2, MSH6, PMS2, EPCAM); **OR**
 - ◇ PALB2; **OR**
 - ◆ Presence of any germline mutation associated with increased pancreatic cancer risk in conjunction with **ANY** of the following clinical indicators of risk:
 - ◇ Dilated pancreatic duct, cystic lesions, or indeterminate findings on CT or MRI; **OR**
 - ◇ Elevated or rising serum CA 19-9 level; **OR**
 - ◇ New-onset or unexplained diabetes; **OR**
 - ◇ Persistent or unexplained abdominal pain; **OR**
 - ◇ Unexplained weight loss^S; **OR**
- Staging (local, regional) of confirmed upper GI tract malignancy when diagnostic imaging is indeterminate without evidence of distant metastasis involving **ANY** of the following:
 - Duodenal ampulla; **OR**
 - Duodenum; **OR**
 - Esophagus; **OR**
 - Jejunum; **OR**
 - Stomach; **OR**

- Tissue sampling is required for **ANY** of the following:
 - Abnormalities or organs adjacent to the GI tract^Y; **OR**
 - Other abdominal or pelvic abnormalities; **OR**
 - Within the GI tract wall (intramural lesions) or adjacent structures (extramural lesions/findings)⁴⁴; **OR**
 - Regional lymph nodes (e.g., mediastinal, peri-esophageal, pre-carinal, peri-gastric, peri-biliary, peri-pancreatic) for **ANY** of the following scenarios¹²:
 - ▲ Enlarged or suspicious for tumor infiltration and sampling might change management; **OR**
 - ▲ Lymphadenopathy is of unknown origin, sampling is likely to affect patient management, and no superficial lymph nodes are easily accessible for percutaneous sampling; **OR**
 - ▲ Normal in size, and random sampling might change the staging designation; **OR**
- EGD with EUS for **ANY** of the following therapeutic indications⁴³:
 - Botulinum toxin into the esophageal muscularis for treatment of achalasia, only if to avoid known adjacent vascular structures (e.g., esophageal varices)¹²; **OR**
 - Celiac plexus block or neurolysis for **ANY** of the following:
 - Palliative treatment of chronic pain related to upper abdominal cancer (including pancreatic cancer); **OR**
 - Relief of chronic pain related to chronic pancreatitis that is unresponsive to medical therapy; **OR**
 - EUS-guided ablation (e.g., thermal, chemotherapeutic) of **ANY** of the following:
 - Certain pancreatic neoplasms; **OR**
 - Certain liver neoplasms, when a percutaneous approach is not feasible or contraindicated; **OR**
 - EUS-directed trans-gastric access to facilitate access to the duodenal papilla via stomach or small bowel segment that has been excluded by prior surgery (e.g., Roux-en-Y gastric bypass); **OR**
 - EUS-guided coil placement for gastric variceal treatment and obliteration; **OR**
 - EUS-guided gastrojejunostomy to relieve/palliate symptoms from gastric outlet obstruction when surgery is not feasible; **OR**
 - EUS-guided portal pressure assessment when transjugular access is not feasible or contraindicated; **OR**
 - Facilitate drainage and decompression via access to a duct (e.g., intrahepatic bile ducts, extrahepatic bile ducts, pancreatic duct) with **ANY** of the following:
 - Adjunct needed with ERCP; **OR**
 - After failed ERCP; **OR**
 - When ERCP is contraindicated; **OR**
 - Placement of radiologic (fiducial) markers into tumors within or adjacent to the wall of the GI tract for surveillance or presurgical marking; **OR**
 - For drainage of symptomatic abdominal fluid collections that can be accessed transmurally⁴⁹; **OR**
 - For drainage of symptomatic pseudocyst or walled-off necrosis by creating a gastroenteric-cyst communication; **OR**
 - Tissue sampling of the liver with EUS-guided liver biopsy when percutaneous or transjugular liver biopsy is not feasible or contraindicated; **OR**
 - Treatment of acute cholecystitis or symptomatic cholelithiasis with EUS-guided gallbladder drainage when surgical treatment is contraindicated or not feasible.

Non-Indications

- An **esophagogastroduodenoscopy (EGD)** is not considered appropriate if **ANY** of the following is **TRUE**:
 - Radiologic imaging with a report that demonstrates **ANY** of the following¹²:
 - Deformed duodenal bulb with **ANY** of the following:

- ☐ Absence of symptoms; **OR**
- ☐ The patient responded adequately to ulcer therapy; **OR**
- ☒ Sliding hiatal hernia (asymptomatic or uncomplicated); **OR**
- ☒ Uncomplicated duodenal ulcer that has responded to therapy; **OR**
- ☐ Complete gastric intestinal metaplasia or focal GIM without dysplasia; **OR**
- ☐ Blockage in the esophagus, stomach, or duodenum is previously established; **OR**
- ☐ The patient has cirrhosis and clinically significant portal hypertension who is on and tolerating continuous non-selective beta-blocker therapy; **OR**
- ☐ Confirmation of gastric band placement; **OR**
- ☐ Confirmation of *Helicobacter pylori* eradication when non-invasive testing (e.g., urease breath test or stool antigen) is readily available⁹; **OR**
- ☐ Diagnosis of laryngopharyngeal reflux when requested without a prior trial of high-dose PPI or PCAB treatment⁷; **OR**
- ☐ Metastatic adenocarcinoma of unknown origin, when results will not alter management; **OR**
- ☐ Optical endomicroscopy is requested; **OR**
- ☐ Perforated viscus is known or suspected⁵⁰; **OR**
- ☐ Peritonitis⁵¹; **OR**
- ☐ Routine screening in asymptomatic patients unless screening for Barrett's, gastroesophageal varices, or gastric neoplasia in a patient with risk factors as noted in indications; **OR**
- ☐ Significant cardiac arrhythmia or recent (within the last 3-6 months) myocardial infarction²; **OR**
- ☐ Surveillance of **ANY** of the following¹²:
 - ☒ Cancer in a patient with pernicious anemia (autoimmune gastropathy), treated achalasia, or prior gastric resection²; **OR**
 - ☒ Healed, benign disease (e.g., esophagitis, gastric, duodenal ulcer)²; **OR**
 - ☒ Repeated dilations of benign strictures unless there is a change in status (e.g., persistent or recurrent dysphagia); **OR**
- ☐ Uncomplicated duodenal ulcer that is responsive to treatment (for *Helicobacter pylori* [*H. pylori*] if positive or to PPI/PCAB); **OR**
- ☐ When lower GI evaluation fully explains symptoms or lab abnormalities.

Definitions and Notes

^AAlarm symptoms: dysphagia or odynophagia, gastrointestinal (GI) bleeding (e.g., hematemesis, melena, anemia, positive stool hemocult), iron deficiency anemia, persistent vomiting, or unexplained weight^{S,35,54}

^BGastroesophageal reflux disease (GERD) symptoms: chest pain, heartburn, or regurgitation⁵²

^CExtraesophageal symptoms: asthma, chronic cough, globus, hoarseness, laryngitis, throat clearing

^DUpper abdominal distress: discomfort, pain, early satiety, epigastric fullness, nausea, vomiting, burning, or pressure that is located between the ribs and navel; symptoms may be present with dyspepsia, GERD, or pancreatitis

^ENon-invasive testing for *Helicobacter pylori* (*H. pylori*): serology, urease breath test, or stool antigen

^FProkinetic therapy: domperidone, erythromycin, or metoclopramide

^GTricyclic antidepressant (TCA): first-generation prescription medication (e.g. amitriptyline, imipramine, or nortriptyline therapy) to treat major depressive disorder, anxiety, chronic pain, and migraines

^HEndoscopic elimination therapy (EET): specialized technology used to destroy Barrett's metaplasia, dysplasia or cancer including: radiofrequency ablation (RFA), cryotherapy/cryoablation, argon plasma coagulation, endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD)

^ICeliac disease symptoms, signs, or laboratory evidence: abdominal pain, B12 deficiency, bloating, chronic diarrhea, confirmed dermatitis herpetiformis, constipation, iron deficiency anemia, steatorrhea, or weight loss/malabsorption

^JOther mucosal abnormalities: thickened fold(s) or asymmetric/symmetric narrowing(s) (stenoses/strictures) of the mucosal lining

^KTreatment prior to a follow-up exam to reassess esophageal histology for confirmed eosinophilic esophagitis (EoE) includes food allergen restriction, proton pump inhibitor (PPI) therapy, steroid therapy (e.g., oral-viscous budesonide or triamcinolone mist), and anti-interleukin therapy (e.g., dupilumab [Dupixent])

^LNon-surgical (i.e., endoscopic) management of achalasia: includes botulinum toxin injection, peroral endoscopic myotomy (POEM), or pneumatic balloon dilation

^MAnemia: hemoglobin less than or equal to 13 g/dL in men and less than or equal to 12 g/dL in women¹²

^NEndoscopic therapy: epinephrine injection, thermal ablation (e.g., bipolar coagulation [BICAP]), argon plasma coagulation (APC), heater probe coagulation, endoclip application, hemostatic spray therapy (e.g., Hemospray), band ligation

^OModern foregut surgery: examples include hiatal hernia repair, fundoplication, bariatric surgery with gastric reduction or with pouch and anastomosis creation (e.g., Roux-en-Y gastric bypass), upper GI reconstruction with partial gastric resection and anastomosis creation (e.g., Billroth I or Billroth II gastrojejunostomy)

^PAt-risk hereditary syndromes: includes Lynch syndrome, juvenile polyposis syndrome, Peutz-Jegher's syndrome, MUTYH-Associated Polyposis (MAP), Li-Fraumeni syndrome, Cowden syndrome, hereditary gastric cancer syndrome^{12,26,27}

^QHigh-incidence nation: an individual who was born and immigrated from a nation identified by the World Health Organization (WHO) who has a higher risk of being diagnosed with an infectious disease; includes Angola, Bangladesh, Brazil, China, Democratic People's Republic of Korea, Democratic Republic of Congo, Ethiopia, India, Indonesia, Kenya, Mozambique, Myanmar, Nigeria, Pakistan, Philippines, South Africa, Thailand, Uganda, United Republic of Tanzania, and Vietnam^{29,53}

^RHigh-risk race or ethnicity: Black, American Indian/Alaska Native (AIAN), Hispanic or Latino/Latina, Black, Native Hawaiian/Pacific Islander (NHPI)^{29,54}

^SUnintended weight loss: loss of more than 10 pounds (or 5% of a patient's body weight) within 6 months or less⁵⁵

^TUncomplicated ulcer: an ulcer that is less than or equal to 2 cm with no bleeding, obstruction, or perforation; symptoms are persistent or recurrent despite treatment

^UDecompensated cirrhosis: cirrhosis with development of clinically overt complications of portal hypertension, including variceal hemorrhage, overt ascites, or hepatic encephalopathy

^VAcutely bleeding, non-variceal lesions: erosions, ulcers, polyps, tumors, Mallory-Weiss tears or vascular lesions (e.g., arteriovenous malformation [AVM], angiodysplasia, or Dieulafoy lesion)

^WAchalasia: esophageal dysmotility disorder characterized by aperistalsis (always) and sometimes by dilated esophagus, barium retention column, bird-beak GE junction, distal esophageal tapering with stricture, and/or EG junction outflow obstruction

^XOperative complications: anastomotic strictures, disruption, fistula, or leak

^YAbnormalities of the GI tract: extramural or intramural lesions (e.g., tumor, mass, nodule, cysts, lymph nodes, sub-epithelial lesions) that involve the lung, liver, gallbladder, bile duct, or pancreas

Medical Evidence

Sengupta et al. (2024) documented the recommendations from the American College of Gastroenterology (ACG) and the Society of Abdominal Radiology (SAR). The recommendations focused on comparing the advantages and limitations of endoscopic versus radiologic diagnostic examinations in patients with gastrointestinal bleeding. The authors noted that, unless contraindicated, the evaluation of non-variceal upper gastrointestinal bleeding begins with esophagogastroduodenoscopy (EGD), with the ideal timing for the procedure being within 24 hours of presentation due to the increased risk of mortality when performed after 24-36 hours.⁵⁶

Guidelines from the ACG and the American Gastroenterological Association (AGA) focused on the use of EGD in high-volume clinical scenarios, including peptic disease, Barrett's esophagus, and celiac disease. The robust guidance is utilized where appropriate in this policy.^{2,14,15,35}

Coelho et al. (2022) reported on a 2022 American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Review of adverse events associated with EGD. Approximately 7 million EGDs were performed annually in the United States during the time period that the ASGE analyzed. The ASGE stated that the procedure is well-tolerated and safe, and the overall incidence of the most insidious complications (e.g., perforation, cardiopulmonary sequelae, and bleeding) remained extraordinarily low. The perforation rate is 1 in 25,000. Evaluation of bleeding requiring emergency department care or inpatient stay for resolution was found in 80 of 100,000 patients within 30 days of the EGD.³

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	02/06/2025	Original Date.
Version 2	03/13/2025	Added indications for endoscopic ultrasound (previously absent) and endoscopic injections (previously absent). Changed policy title to "Esophagogastroduodenoscopy [EGD]" - prior title was considered less inclusive of the current range of indications. Updated the Medical Evidence section for relevance. Added references.
Version 3	02/12/2026	Annual review. Added CPT codes: 43191-43198, 43200-43202, 43226, 43233, 43236, 43240-43241, 43243-43251, 43254-43255, 43257, 43270, 43497, 43499, 43999. Rearranged bullets for improved usability and organization. Updated sections for gastroesophageal reflux disease (GERD), Barrett's esophagus, caustic ingestion, atypical chest pain, celiac disease, confirmation of histologic diagnosis of a radiologically demonstrated lesion, eosinophilic esophagitis (EoE), peptic ulcer disease, surveillance for upper GI cancer or pre-cancer, suspected inflammation of the upper gastrointestinal (GI) tract, upper GI tract screening or surveillance for possible esophageal or gastroduodenal polyps or cancer. The evaluation section includes additional criteria. Updated the sections for esophagogastroduodenoscopy (EGD) with endoscopic ultrasound (EUS) for therapeutic and diagnostic indications. Added indications for upper abdominal distress (previously under "dyspepsia"), monitoring of gastric pre-malignant conditions, pediatric patients, tissue sampling, surveillance of portal hypertension and esophagogastric varices, and therapeutic treatment. Removed indications for routine surveillance of non-dysplastic disease, surveillance after treatment for dysplasia, effects of nonsteroidal anti-inflammatory drug (NSAID), erosive reflux esophagitis, heartburn, nausea, planning for anti-reflux surgery, prolonged anorexia, routine screening for non-bleeding esophagogastric varices, and serial follow-up. Updated non-indications for confirmation of Helicobacter pylori (H. pylori), diagnosis of laryngopharyngeal reflux, and uncomplicated duodenal ulcer. Added non-indications for radiologic imaging, absence of GI symptoms or high-risk histology with additional criteria, cirrhosis and portal hypertension, metastatic adenocarcinoma of unknown origin, optical endomicroscopy, routine screening in asymptomatic patients, surveillance for repeated dilations. Removed non-indications for staging of tumors shown to be metastatic by other imaging methods, symptoms that are functional in origin, and toxic megacolon in an unstable patient. Added Definitions section. Added references 1, 3-6, 10-14, 17, 20-21, 23-25, 27-31, 37-41, 43-45, 47-55.



Cohere Medical Policy - Esophagogastroduodenoscopy (EGD)

Clinical Guidelines for Medical Necessity Review

Version: 2
Revision Date: March 13, 2025

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Guideline Information:

Specialty Area: Gastroenterology

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Medical Necessity Criteria

Service: Esophagogastroduodenoscopy (EGD)

Recommended Clinical Approach

Esophagogastroduodenoscopy (EGD) is an upper intestinal endoscopy technique used to examine, obtain samples, or treat pathological conditions of the upper intestinal tract. EGD is performed with a lighted, flexible, fiberoptic instrument, usually less than 12 mm in diameter, passed through the cricopharynx. The patient receives conscious sedation, and a topical anesthetic may be applied to the posterior pharynx. The entire esophagus, stomach, and duodenum can be visualized with EGD. Endoscopic ultrasound (EUS) or transendoscopic ultrasound uses a transducer at the end of an endoscope to obtain high-resolution images that improve visualization of the gastrointestinal tract and allow evaluation of adjacent structures, including the pancreas and biliary tree.

Diagnostic EGD is used to visualize the oropharynx, esophagus, stomach, and proximal duodenum and is useful for detecting conditions such as focal benign or malignant lesions, diffuse mucosal changes, luminal obstruction, abnormal motility, and extrinsic compression by contiguous structures.¹ A diagnostic EGD allows the examiner to visualize abnormalities detectable by the technique and to photograph and collect a biopsy sample as appropriate. An endoscopic Doppler probe can be used as an adjunct diagnostic modality to assess the treatment's local blood supply efficacy and to stratify patients at higher risk of repeat upper gastrointestinal bleeding (UGIB). Pulsatile Doppler signals can indicate the presence and path of bleeding vessels. The probe can also determine if vessels were appropriately coagulated following endoscopic hemostasis. The absence of a Doppler signal is consistent with successful hemostasis of a bleeding lesion. Lesions with a persistent dopplerable signal have a higher risk for rebleeding.²

EGD is generally considered a safe procedure, although bleeding, perforation, infection, acute pancreatitis³, and sedation-related complications⁴ following the procedure have been reported in rare instances.⁵

Medical Necessity Criteria

Indications

→ **Esophagogastroduodenoscopy (EGD)** is considered appropriate if **ANY** of the following is **TRUE**^{1,6,24,26}:

- ◆ Gastroesophageal reflux disease (GERD) symptoms (e.g., heartburn, regurgitation, or chest pain) that persist despite treatment⁵⁻⁶; **OR**
- ◆ A single screening exam for GERD with **AT LEAST THREE** of the following risk factors for concurrent Barrett's esophagus^{1,5}:
 - Prolonged GERD for more than 5 years; **OR**
 - The age of the patient is greater than 50 years; **OR**
 - Male gender; **OR**
 - Hiatal hernia⁷⁻⁸; **OR**
 - Current or past tobacco use; **OR**
 - Obesity; **OR**
 - Family history of Barrett's esophagus in a first-degree relative; **OR**
 - Family history of esophageal adenocarcinoma in a first-degree relative; **OR**
- ◆ Planning for anti-reflux surgery⁹; **OR**
- ◆ Nausea that is persistent and unexplained⁶; **OR**
- ◆ Vomiting that is persistent and unexplained⁵⁻⁶; **OR**
- ◆ Atypical chest pain after cardiac disease has been ruled out⁶; **OR**
- ◆ Heartburn with alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss)^{8,10}; **OR**
- ◆ Prolonged anorexia⁵; **OR**
- ◆ Unexplained weight loss⁵; **OR**
- ◆ Effects of nonsteroidal anti-inflammatory drug (NSAID) use¹¹; **OR**
- ◆ Barrett's esophagus is present, and the patient requires **ANY** of the following¹²:
 - Routine surveillance of non-dysplastic disease every 3 to 5 years^{1,13}; **OR**
 - Reassessment during treatment to eliminate dysplasia (e.g., ablation, mucosal resection, mucosal dissection) every 3 to 6 months¹²; **OR**
 - Surveillance after completion of treatment for dysplasia when **ANY** of the following is **TRUE**¹:

- For low-grade dysplasia – every 6 months for 1 year, then annually thereafter; **OR**
 - For high-grade dysplasia – every 3 months for 1 year, then every 6 months for 1 year, then annually thereafter; **OR**
- ◆ Swallowing symptoms including, but not limited to, **ANY** of the following:
 - Difficulty swallowing (e.g., dysphagia); **OR**
 - Pain while swallowing (odynophagia); **OR**
- ◆ Esophageal dysmotility based on barium radiography or esophageal manometry, when suggestive of achalasia¹⁴; **OR**
- ◆ Confirmation and specific histologic diagnosis of radiologically demonstrated lesions, including, but not limited to, **ANY** of the following¹⁴⁻¹⁷:
 - Protrusions/growths from, within, or extrinsic to the mucosal wall; **OR**
 - Excavated lesions, such as erosions, ulcers, or diverticula; **OR**
 - Other mucosal abnormalities, including thickened fold(s) or asymmetric/symmetric narrowing(s) (stenoses/strictures); **OR**
- ◆ Clarification of location or pathology of a lesion during surgery¹⁸; **OR**
- ◆ Evaluation for possible gastric or duodenal polyps in patients with familial adenomatous polyposis or other at-risk hereditary syndromes (e.g., Lynch syndrome, juvenile polyposis syndrome, Peutz-Jegher's syndrome, MUTYH-Associated Polyposis [MAP], Li-Fraumeni syndrome, Cowden syndrome, hereditary gastric cancer syndrome)¹⁹; **OR**
- ◆ The patient is less than 60 years of age and has dyspepsia with **ANY** of the following:
 - Negative *Helicobacter pylori* test and no response to proton pump inhibitor (PPI) therapy^{6,20-21}; **OR**
 - Equivocal results from non-invasive *Helicobacter pylori* testing and need for gastric biopsy²¹⁻²²; **OR**
 - A one-time screening in a patient with a family history of upper GI malignancy in a first-degree relative; **OR**
 - Lymphadenopathy (e.g., supraclavicular, periumbilical); **OR**

- Palpable abdominal mass; **OR**
- Alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss, dysphagia/odynophagia); **OR**
- ◆ The patient is 60 years of age or older and has dyspepsia; **OR**
- ◆ Peptic ulcer disease with **ANY** of the following²³⁻²⁴:
 - Persistent or recurrent symptoms despite treatment; **OR**
 - Recent identification of gastric or duodenal ulcer, to document ulcer healing after treatment for at least 2 months, even without symptoms; **OR**
- ◆ Erosive reflux esophagitis with **ANY** of the following^{2,23}:
 - Persistent or recurrent symptoms despite appropriate GERD treatment; **OR**
 - To document healing after treatment of LA grade C or D esophagitis and to exclude the development of Barrett's esophagus; **OR**
- ◆ Surveillance as determined by the endoscopist for or suspected recurrence of prior upper GI cancer or pre-cancer, including **ANY** of the following²³:
 - Squamous cell carcinoma of the esophagus; **OR**
 - Adenocarcinoma of the esophagus; **OR**
 - Adenocarcinoma or mucosa-associated lymphoma (MALT) of the stomach; **OR**
 - Adenocarcinoma of duodenum or ampulla; **OR**
 - Stromal/neuroendocrine tumor of the esophagus, stomach, or duodenum; **OR**
 - Other subepithelial pre-malignant lesion of the esophagus, stomach, or duodenum; **OR**
 - Adenomatous polyp of stomach, duodenum, or ampulla; **OR**
 - Dysplasia (low or high grade) in patients with gastric intestinal metaplasia or chronic atrophic gastritis; **OR**
- ◆ Confirmed or suspected eosinophilic esophagitis (EoE) for **ANY** of the following²⁵:
 - Initial exam for suspected EoE for evaluation of dysphagia, GERD symptoms refractory to PPI therapy, or history of esophageal food bolus impaction; **OR**
 - Follow-up exam to reassess esophageal histology for confirmed EoE, after treatment (e.g., food allergen

- restriction, PPI therapy, steroid therapy, anti-interleukin therapy); **OR**
- Follow-up exam to reassess esophagus when symptoms recur on previously effective therapy; **OR**
- ◆ Evaluation of chronic diarrhea to identify an upper GI etiology (e.g., celiac disease) when small bowel disease is suspected; **OR**
- ◆ Suspected celiac disease based on **ANY** of the following²⁶:
 - Typical signs or symptoms (e.g., abdominal pain, diarrhea, constipation, weight loss without intent, iron deficiency anemia); **OR**
 - Abnormal celiac serology including **ANY** of the following:
 - Elevated tissue transglutaminase immunoglobulin A (TTG IgA) with normal total IgA; **OR**
 - Elevated endomysial IgA with normal total IgA; **OR**
 - Elevated deamidated anti-gliadin IgG with IgA deficiency; **OR**
 - The patient is at a high-risk based on celiac human leucocyte antigen (HLA) analysis; **OR**
- ◆ Known celiac disease with **ANY** of the following²⁶:
 - The patient has been on a gluten-free diet for at least 1 year and requires histologic confirmation of remission; **OR**
 - Symptoms persist despite adherence to a gluten-free diet for at least 6 months; **OR**
- ◆ Acute injury including, but not limited to, **ANY** of the following:
 - Caustic agent ingested; **OR**
 - Sharp foreign object ingested²⁷; **OR**
- ◆ Evaluation for esophagogastric varices (swollen veins [varices] in the esophageal or gastric wall) due to suspicion for or confirmation of liver cirrhosis or portal hypertension²⁸; **OR**
- ◆ Routine screening (every 3 years) or surveillance (every 1-2 years) of non-bleeding esophagogastric varices²⁸⁻²⁹; **OR**
- ◆ Evaluation of GI bleeding and **ANY** of the following:
 - Upper GI symptoms; **OR**
 - Presumed chronic blood loss (iron deficiency anemia, positive fecal occult blood test, or both) when colonoscopy is negative³⁰; **OR**
 - Active bleeding is present (hematemesis, melena, or hematochezia); **OR**

- Recent active bleeding (within 72 hrs) and etiology remains unknown; **OR**
- Suspected aorto-enteric fistula; **OR**
- Re-bleeding occurs after recent endoscopic therapy; **OR**
- Surgery is being considered; **OR**
- ◆ Suspected inflammation of the upper gastrointestinal (GI) tract from etiologies including, but not limited to, inflammatory myositis, Crohn's disease, ulcerative colitis, inflammatory bowel disease (IBD), and acute graft versus host disease³¹⁻³²; **OR**
- ◆ Conditions in which upper GI pathology might modify other planned management, such as patients with **ANY** of the following⁵:
 - Organ transplantation is planned; **OR**
 - Long-term anticoagulation therapy; **OR**
 - Long-term nonsteroidal anti-inflammatory drug therapy for arthritis; **OR**
 - Cancer of the head and neck; **OR**
 - Bariatric surgery is planned; **OR**³³
- ◆ EGD with endoscopic ultrasound is considered appropriate with **ANY** of the following³⁸⁻⁵⁰:
 - **ANY** of the following diagnostic indications *not requiring* intramural or transmural fine needle aspiration/biopsy:
 - When initial ultrasound, CT scan, or MRI is nondiagnostic or inconclusive and clinical suspicion remains high for **ANY** of the following known or suspected conditions:
 - ◆ Cholelithiasis; **OR**
 - ◆ Choledocholithiasis; **OR**
 - ◆ Biliary stricture or obstruction; **OR**
 - ◆ Structural or congenital abnormality; **OR**
 - For local and regional staging of confirmed malignancy involving the esophagus, stomach, duodenum, duodenal ampulla, bile duct, pancreas or jejunum when diagnostic imaging is insufficient or indeterminate; **OR**
 - For evaluation of possible etiologies for unexplained acute or recurrent pancreatitis; **OR**

- **ANY** of the following diagnostic indications *that include* intramural or transmural fine needle aspiration/biopsy of/for:
 - Tumor/mass/sub-epithelial lesions involving the upper GI tract (esophagus, stomach, duodenum, duodenal ampulla, jejunum); **OR**
 - Tumor/mass/lesions/cysts involving regional adjacent organs (lung, liver, gallbladder, bile duct, pancreas); **OR**
 - Regional lymph nodes (e.g., mediastinal, peri-esophageal, pre-carinal, peri-gastric, peri-biliary, peri-pancreatic) for **ANY** of the following scenarios:
 - ◆ When enlarged or suspicious for tumor infiltration and sampling might change management; **OR**
 - ◆ When normal in size and random sampling might change staging designation; **OR**
 - ◆ when lymphadenopathy is of unknown origin, sampling is likely to affect patient management, and no superficial lymph nodes are easily accessible for percutaneous sampling; **OR**
 - Confirmation of suspected autoimmune pancreatitis when diagnostic imaging and/or serologic testing is inconclusive; **OR**
 - Exclusion or confirmation of chronic pancreatitis as a possible etiology for chronic unexplained upper abdominal pain; **OR**
- **ANY** of the following *therapeutic* indications:
 - For bile duct or pancreatic duct access to achieve drainage or other therapy (e.g., stent placement, stone removal) if access could not be achieved by ERCP; **OR**
 - For drainage of symptomatic abdominal fluid collections that can be accessed transmurally from the esophagus, stomach or duodenum, including

abscesses, bilomas, pseudocysts, or other pancreatic fluid collections; **OR**

- For creation of a gastroenterostomy for **ANY** of the following:
 - ◆ relieve/palliate symptoms from gastric outlet obstruction when surgery is not feasible; **OR**
 - ◆ facilitate access to the duodenal papilla via stomach or small bowel segment that has been excluded by prior surgery; **OR**
- For transmural injection of therapeutic agents (e.g., ethanol, phenol) including **ANY** of the following:
 - ◆ Neurolytic agent (e.g., botulinum toxin, ethanol, phenol) into the celiac plexus for **ANY** of the following:
 - Palliate chronic pain related to upper abdominal cancer (including pancreatic cancer); **OR**
 - Relieve chronic pain related to chronic pancreatitis that is unresponsive to medical therapy; **OR**
 - Identify/predict surgical success in patients with median arcuate ligament syndrome (MALS) ⁵¹⁻⁵³; **OR**
 - ◆ Botulinum toxin into the esophageal muscularis for treatment of achalasia; **OR**
- For transmural delivery of targeted cancer treatment (e.g., radiofrequency ablation, chemotherapy); **OR**
- For transmural placement of fiducial markers in tumors for surveillance or presurgical marking.

Non-Indications

→ **Diagnostic esophagogastroduodenoscopy (EGD)** is not considered appropriate if **ANY** of the following is **TRUE** ^{1,6,24,26}:

- ◆ Blockage in the esophagus, stomach, or duodenum is previously established; **OR**
- ◆ Surveillance of healed, benign disease, such as gastric or duodenal ulcer or benign esophageal strictures¹; **OR**
- ◆ Confirming *Helicobacter pylori* eradication; **OR**

- ◆ Cancer surveillance in patients with pernicious anemia, treated achalasia, or prior gastric resection¹; **OR**
- ◆ Patients with significant cardiac arrhythmia or recent (within the last 3–6 months) myocardial infarction¹; **OR**
- ◆ Perforated bowel; **OR**
- ◆ Peritonitis; **OR**
- ◆ Toxic megacolon in an unstable patient; **OR**
- ◆ Perforated viscus is known or suspected; **OR**
- ◆ Before bariatric surgery in asymptomatic individuals; **OR**
- ◆ Confirming placement of gastric band; **OR**
- ◆ Diagnosing laryngopharyngeal reflux; **OR**
- ◆ Optical endomicroscopy is requested.

*Note: Patients undergoing dilations, percutaneous endoscopic gastrostomy [PEG], polypectomy, endoscopic sphincterotomy, endoscopic ultrasound-guided fine-needle aspiration [FNA], laser ablation, and coagulation are at higher risk for bleeding, and adjustment of anticoagulation may be necessary.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures

43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis.

Medical Evidence

Sengupta et al. (2024) documented the recommendations of a panel of experts from the American College of Gastroenterology and the Society of Abdominal Radiology, comparing the advantages and limitations of endoscopic versus radiologic diagnostic examinations in patients with gastrointestinal bleeding. The authors noted that unless contraindicated, the evaluation of non-variceal upper gastrointestinal bleeding begins with EGD, with the ideal timing for the procedure being within 24 hours of presentation due to the increased risk of mortality when performed greater than 24–36 hours.^{[37](#)}

The European Society of Gastrointestinal Endoscopy (ESGE) published a technical review of endoscopic ultrasound in 2022. The authors discussed several scenarios wherein endoscopic ultrasound is the optimal diagnostic or therapeutic modality, such as the drainage of fluid collections, biopsy of suspicious lesions, and surveillance and staging of neoplasms.^{[38](#)}

A 2022 American Society of Gastrointestinal Endoscopy (ASGE) standards of practice review of adverse events associated with EGD found this procedure to be well-tolerated and safe, with more than 7 million esophagogastroduodenoscopies taking place each year in the United States. The overall incidence of the most insidious complications, including perforation, cardiopulmonary sequelae, and bleeding, remains extraordinarily low. Rates of perforation, for example, have been estimated at 1 in 25,000. Bleeding requiring emergency department care or inpatient stay for resolution has been evaluated at 80 in 100,000 patients within 30 days of the EGD.^{[5](#)}

The American College of Gastroenterologists (ACG) and the American Gastroenterological Association (AGA) have published several recent guidelines pertaining to the use of EGD in high-volume clinical scenarios, such as peptic disease, Barrett's esophagus, and celiac disease. This robust guidance has been utilized where appropriate to synthesize this policy.^{[16,24,26](#)}

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Clinical Guideline Revision History/Information

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Review History		
Version 2	3/13/2025	• Added indications for endoscopic ultrasound (previously absent) and endoscopic injections (previously absent). • Changed policy title to "Esophagogastroduodenoscopy [EGD]" - prior title was considered less inclusive of current range of indications . • Rewrote medical evidence section for relevance. • Added references



Cohere Medical Policy - Diagnostic Esophagogastroduodenoscopy (EGD)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: February 6, 2025

Important Notices

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Medical Necessity Criteria

Service: Diagnostic Esophagogastroduodenoscopy (EGD)

Recommended Clinical Approach

Esophagogastroduodenoscopy (EGD) is an upper intestinal endoscopy technique used to examine, obtain samples, or treat pathological conditions of the upper intestinal tract. EGD is performed with a lighted, flexible, fiberoptic instrument, usually less than 12 mm in diameter, passed through the cricopharynx. The patient receives conscious sedation, and a topical anesthetic may be applied to the posterior pharynx. The entire esophagus, stomach, and duodenum can be visualized with EGD. Endoscopic ultrasound (EUS) or transendoscopic ultrasound uses a transducer at the end of an endoscope to obtain high-resolution images that improve visualization of the gastrointestinal tract and allow evaluation of adjacent structures, including the pancreas and biliary tree.

Diagnostic EGD is used to visualize the oropharynx, esophagus, stomach, and proximal duodenum and is useful for detecting conditions such as focal benign or malignant lesions, diffuse mucosal changes, luminal obstruction, abnormal motility, and extrinsic compression by contiguous structures.¹ A diagnostic EGD allows the examiner to visualize abnormalities detectable by the technique and to photograph and collect a biopsy sample as appropriate. An endoscopic Doppler probe can be used as an adjunct diagnostic modality to assess the treatment's local blood supply efficacy and to stratify patients at higher risk of repeat upper gastrointestinal bleeding (UGIB). Pulsatile Doppler signals can indicate the presence and path of bleeding vessels. The probe can also determine if vessels were appropriately coagulated following endoscopic hemostasis. The absence of a Doppler signal is consistent with successful hemostasis of a bleeding lesion. Lesions with a persistent dopplerable signal have a higher risk for rebleeding.²

EGD is generally considered a safe procedure, although bleeding, perforation, infection, acute pancreatitis³, and sedation-related complications⁴ following the procedure have been reported in rare instances.⁵

Medical Necessity Criteria

Indications

- **Diagnostic esophagogastroduodenoscopy (EGD)** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Gastroesophageal reflux disease (GERD) symptoms (e.g., heartburn, regurgitation, or chest pain) that persist despite treatment⁵⁻⁶; **OR**
 - ◆ A single screening exam for GERD with **AT LEAST THREE** of the following risk factors for concurrent Barrett's esophagus^{1,5}:
 - Prolonged GERD for more than 5 years; **OR**
 - The age of the patient is greater than 50 years; **OR**
 - Male gender; **OR**
 - Hiatal hernia⁷⁻⁸; **OR**
 - Current or past tobacco use; **OR**
 - Obesity; **OR**
 - Family history of Barrett's esophagus in a first-degree relative; **OR**
 - Family history of esophageal adenocarcinoma in a first-degree relative; **OR**
 - ◆ Planning anti-reflux surgery⁹; **OR**
 - ◆ Nausea that is persistent and unexplained⁶; **OR**
 - ◆ Vomiting that is persistent and unexplained⁵⁻⁶; **OR**
 - ◆ Atypical chest pain after cardiac disease has been ruled out⁶; **OR**
 - ◆ Heartburn with alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss)^{8,10}; **OR**
 - ◆ Prolonged anorexia⁵; **OR**
 - ◆ Unexplained weight loss⁵; **OR**
 - ◆ Effects of nonsteroidal anti-inflammatory drug (NSAID) use¹¹; **OR**
 - ◆ Barrett's esophagus is present, and the patient requires **ALL** of the following¹²:
 - Routine surveillance of non-dysplastic disease every 3 to 5 years^{1,13}; **AND**
 - Reassessment during treatment to eliminate dysplasia (e.g., ablation, mucosal resection, mucosal dissection) every 3 to 6 months¹²; **AND**
 - Surveillance after completion of treatment for dysplasia when **ANY** of the following is **TRUE**¹:

- For low-grade dysplasia – every 6 months for 1 year, then annually thereafter; **OR**
 - For high-grade dysplasia – every 3 months for 1 year, then every 6 months for 1 year, then annually thereafter; **OR**
- ◆ Swallowing symptoms including, but not limited to, **ANY** of the following:
 - Difficulty swallowing (e.g., dysphagia); **OR**
 - Pain while swallowing (odynophagia); **OR**
- ◆ Esophageal dysmotility based on barium radiography or esophageal manometry, when suggestive of achalasia¹⁴; **OR**
- ◆ Confirmation and specific histologic diagnosis of radiologically demonstrated lesions, including, but not limited to, **ANY** of the following¹⁴⁻¹⁷:
 - Protrusions/growths from, within, or extrinsic to the mucosal wall; **OR**
 - Excavated lesions, such as erosions, ulcers, or diverticula; **OR**
 - Other mucosal abnormalities, including thickened fold(s) or asymmetric/symmetric narrowing(s) (stenoses/strictures); **OR**
- ◆ Clarification of location or pathology of a lesion during surgery¹⁸; **OR**
- ◆ Evaluation for possible gastric or duodenal polyps in patients with familial adenomatous polyposis or other at-risk hereditary syndromes (e.g., Lynch syndrome, juvenile polyposis syndrome, Peutz-Jegher's syndrome, MUTYH-Associated Polyposis [MAP], Li-Fraumeni syndrome, Cowden syndrome, hereditary gastric cancer syndrome)¹⁹; **OR**
- ◆ The patient is less than 60 years of age and has dyspepsia with **ANY** of the following:
 - Negative *Helicobacter pylori* test and no response to proton pump inhibitor (PPI) therapy^{6,20-21}; **OR**
 - Equivocal results from non-invasive *Helicobacter pylori* testing and need for gastric biopsy²¹⁻²²; **OR**
 - A one-time screening in a patient with a family history of upper GI malignancy in a first-degree relative; **OR**
 - Lymphadenopathy (e.g., supraclavicular, periumbilical); **OR**
 - Palpable abdominal mass; **OR**

- Alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss, dysphagia/odynophagia); **OR**
- ◆ The patient is 60 years of age or older and has dyspepsia; **OR**
- ◆ Peptic ulcer disease with **ANY** of the following²³⁻²⁴:
 - Persistent or recurrent symptoms despite treatment; **OR**
 - Recent identification of gastric or duodenal ulcer, to document ulcer healing after treatment for at least 2 months, even without symptoms; **OR**
- ◆ Erosive reflux esophagitis with **ANY** of the following^{2,23}:
 - Persistent or recurrent symptoms despite appropriate GERD treatment; **OR**
 - To document healing after treatment of grade C or D esophagitis and to exclude the development of Barrett's esophagus; **OR**
- ◆ Surveillance as determined by the endoscopist for or suspected recurrence of prior upper GI cancer or pre-cancer, including **ANY** of the following²³:
 - Squamous cell carcinoma of the esophagus; **OR**
 - Adenocarcinoma of the esophagus; **OR**
 - Adenocarcinoma or mucosa-associated lymphoma (MALT) of the stomach; **OR**
 - Adenocarcinoma of duodenum or ampulla; **OR**
 - Stromal/neuroendocrine tumor of the esophagus, stomach, or duodenum; **OR**
 - Other subepithelial pre-malignant lesion of the esophagus, stomach, or duodenum; **OR**
 - Adenomatous polyp of stomach, duodenum, or ampulla; **OR**
 - Dysplasia (low or high grade) in patients with gastric intestinal metaplasia or chronic atrophic gastritis; **OR**
- ◆ Confirmed or suspected eosinophilic esophagitis (EoE) for **ANY** of the following²⁵:
 - Initial exam for suspected EoE for evaluation of dysphagia, GERD symptoms refractory to PPI therapy, or history of esophageal food bolus impaction; **OR**
 - Follow-up exam to reassess esophageal histology for confirmed EoE, after treatment (e.g., food allergen restriction, PPI therapy, steroid therapy, anti-interleukin therapy); **OR**

- Follow-up exam to reassess esophagus when symptoms recur on previously effective therapy; **OR**
- ◆ Evaluation of chronic diarrhea to identify an upper GI etiology (e.g., celiac disease) when small bowel disease is suspected; **OR**
- ◆ Suspected celiac disease based on **ANY** of the following²⁶:
 - Typical signs or symptoms (e.g., abdominal pain, diarrhea, constipation, weight loss without intent, iron deficiency anemia); **OR**
 - Abnormal celiac serology including **ANY** of the following:
 - Elevated tissue transglutaminase immunoglobulin A (TTG IgA) with normal total IgA; **OR**
 - Elevated endomysial IgA with normal total IgA; **OR**
 - Elevated deamidated anti-gliadin IgG with IgA deficiency; **OR**
 - The patient is at a high-risk based on celiac human leucocyte antigen (HLA) analysis; **OR**
- ◆ Known celiac disease with **ANY** of the following²⁶:
 - The patient has been on a gluten-free diet for at least 1 year and requires histologic confirmation of remission; **OR**
 - Symptoms persist despite adherence to a gluten-free diet for at least 6 months; **OR**
- ◆ Acute injury including, but not limited to, **ANY** of the following:
 - Caustic agent ingested; **OR**
 - Sharp foreign object ingested²⁷; **OR**
- ◆ Evaluation for esophagogastric varices (swollen veins [varices] in the esophageal or gastric wall) due to suspicion for or confirmation of liver cirrhosis or portal hypertension²⁸; **OR**
- ◆ Routine surveillance of non-bleeding esophagogastric varices every 3 years²⁸⁻²⁹; **OR**
- ◆ Evaluation of GI bleeding and **ANY** of the following:
 - Upper GI symptoms; **OR**
 - Melena (dark stool); **OR**
 - Presumed chronic blood loss (iron deficiency anemia, positive fecal occult blood test, or both) when colonoscopy is negative³⁰; **OR**
 - Active bleeding is present (hematemesis, melena, or hematochezia); **OR**
 - Recent active bleeding (within 72 hrs) and etiology remain unknown; **OR**

- Suspected aorto-enteric fistula; **OR**
- Re-bleeding occurs after recent endoscopic therapy; **OR**
- Surgery is being considered; **OR**
- ◆ Suspected inflammation of the upper gastrointestinal (GI) tract from etiologies including, but not limited to, inflammatory myositis, Crohn's disease, ulcerative colitis, inflammatory bowel disease (IBD), and acute graft versus host disease³¹⁻³²; **OR**
- ◆ Conditions in which upper GI pathology might modify other planned management, such as patients with **ANY** of the following⁵:
 - Organ transplantation is planned; **OR**
 - Long-term anticoagulation therapy; **OR**
 - Long-term nonsteroidal anti-inflammatory drug therapy for arthritis; **OR**
 - Cancer of the head and neck; **OR**
 - Bariatric surgery is planned.³³

Non-Indications

- **Diagnostic esophagogastroduodenoscopy (EGD)** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Blockage in the esophagus, stomach, or duodenum is previously established; **OR**
 - ◆ Surveillance of healed, benign disease, such as gastric or duodenal ulcer or benign esophageal strictures¹; **OR**
 - ◆ Confirming *Helicobacter pylori* eradication; **OR**
 - ◆ Cancer surveillance in patients with pernicious anemia, treated achalasia, or prior gastric resection¹; **OR**
 - ◆ Patients with cardiac arrhythmia or recent myocardial infarction¹; **OR**
 - ◆ Perforated bowel; **OR**
 - ◆ Peritonitis; **OR**
 - ◆ Toxic megacolon in an unstable patient; **OR**
 - ◆ Perforated viscus is known or suspected; **OR**
 - ◆ Before bariatric surgery in asymptomatic individuals; **OR**
 - ◆ Confirming placement of gastric band; **OR**
 - ◆ Diagnosing laryngopharyngeal reflux.

*Note: Patients undergoing dilations, percutaneous endoscopic gastrostomy [PEG], polypectomy, endoscopic sphincterotomy, endoscopic ultrasound-guided fine-needle aspiration [FNA], laser ablation, and coagulation are at higher risk for bleeding, and adjustment of anticoagulation may be necessary.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)

43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis.

Medical Evidence

Gyawali et al. (2020) recommend the use of ambulatory reflux monitoring over the assessment of response to proton pump inhibitor (PPI) therapy for a conclusive diagnosis of gastroesophageal reflux disease (GERD) in patients with esophageal reflux symptoms. The increasing popularity of PPI trials for suspected GERD symptoms has decreased the likelihood of finding reflux esophagitis using EGD. In this study, among 696 patients undergoing EGD for suspected GERD symptoms, those without reflux esophagitis were more likely to be on PPI therapy than those with erosive esophagitis (53% versus 29%, $P < 0.001$). Among over 700 patients with a partial response to PPI therapy, only 20% to 30% had esophageal mucosal breaks on EGD. Therefore, despite high specificity, EGD has low sensitivity when diagnosing GERD. However, the authors note high-quality EGD is essential before further evaluating esophageal symptoms.³⁴

Schuldt et al. (2019) evaluated the demand for nasal EGD with ultrathin endoscopes as an alternative to diagnostic peroral EGD. Nasal EGD has been considered to reduce patients' discomfort and anxiety and avoid sedation-related adverse effects. In the study, among outpatients with no contraindications for nasal EGD, 60% chose nasal EGD, underscoring an existing demand for nasal EGD in outpatients. Of the 196 patients eligible for the study, 77% had previously undergone peroral EGD. Of the patients who underwent nasal EGD, 83% were fairly to extremely satisfied with the procedure. Patients who chose a specific procedure (peroral or nasal EGD) were more likely to select the same procedure as their future preference. This preference was unaffected by the procedure that patients chose previously.³⁵

Mazzeffi et al. (2021) evaluated the efficacy of high-flow nasal cannula (HFNC) oxygen in reducing the incidence of hypoxemia during anesthesia for advanced EGD. In a randomized controlled trial (RCT) that included 262 adult patients undergoing anesthesia for advanced EGD, HFNC oxygen significantly reduced the incidence of one or more hypoxemia events from 33.1% to 21.2%.³⁶

Sengupta et al. (2024) documented the recommendations of a panel of experts from the American College of Gastroenterology and the Society of Abdominal Radiology, including comparing the advantages and limitations of

endoscopic versus radiologic diagnostic examinations in patients with gastrointestinal bleeding. The authors note that unless contraindicated, the evaluation of non-variceal upper gastrointestinal bleeding begins with EGD, with the ideal timing for the procedure being within 24 hours of presentation, with high mortality seen when performed early (less than 6-12 hours) or later (greater than 24-36 hours).³⁷

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Original Date: February 6, 2025		
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Cohere Medical Policy – Gastric Pacing/Electrical Stimulation

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Gastroenterology/Urology/Disorders of the Musculoskeletal System

Guideline Name: Cohere Medical Policy - Gastric Pacing/Electrical Stimulation

Date of last literature review: 1/24/2025

Document last updated: 2/5/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Gastric Pacing/Electrical Stimulation

Recommended Clinical Approach

Electrical stimulation is a treatment modality that modulates the inappropriate or excessive activity of nerves through the surgical implantation of a device that generates an electrical pulse to stimulate the nerves of a specific region. Several types of neurostimulators exist.

- Gastric electrical stimulation (GES) is an advanced treatment for gastroparesis, a condition that manifests as delayed movement of food from the stomach to the small intestine. This may result in chronic nausea, vomiting, abdominal pain, bloating, and nutritional deficiency. Although gastroparesis may be well-controlled through less invasive methods, including dietary modification and medical therapy, a small percentage of patients experience refractory gastroparesis that causes intractable nausea and vomiting. Among such patients, gastric electrical stimulation is indicated, wherein a neurostimulator device is surgically placed beneath the skin to direct electrical impulses to the smooth muscle of the stomach. For appropriately selected patients, this often confers an improvement in symptoms and an overall improved quality of life.
- More than one-fifth of adults in the United States suffer from chronic pain. Peripheral nerve stimulation is approved by the US Food & Drug Administration for the treatment of chronic pain affecting the lower back, extremities, trunk, head, and face. A neurostimulator device is implanted in the appropriate area, and electrodes are placed near the affected peripheral nerves (i.e., nerves located outside of the brain and spinal cord). It is reserved for patients who have not attained adequate pain control through conventional treatment. Although the evidence base is growing, there is not yet enough research to validate this tool as an effective, safe means to control pain. This service is clinically unproven and not medically necessary at this time.
- Fecal incontinence and urinary complications are the primary indications for sacral neurostimulation. The neurostimulator device is positioned to deliver electrical impulses to the sacral nerves, which

control bowel and bladder function. It is an advanced tool for patients who have failed conventional, conservative therapy. Patient outcomes and quality of life are improved among appropriately selected patients.

Medical Necessity Criteria

Indications

→ **Electrical neurostimulation** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **Gastric electrical stimulation (GES)** is considered appropriate if **ALL** of the following are **TRUE**¹⁻³:

- Documented confirmation of gastroparesis (gastric emptying delay with >10% tracer retention at 4 hours) on a 4-hour scintigraphic gastric emptying test; **AND**
- Predominant symptom is nausea or vomiting; **AND**
- Other anatomic/organic cause for symptoms has been excluded with upper endoscopy and selective imaging, if clinically indicated; **AND**
- Failure of **ALL** of the following:
 - Dietary modification (adoption of a small particle diet); **AND**
 - Over-the-counter (OTC) therapy; **AND**
 - Anti-emetics; **AND**
 - Prokinetics; **OR**

◆ **Sacral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**^{4,5}:

- Successful stimulation trial/test period of sacral nerve stimulation with at least a 50% reduction in symptoms compared to baseline; **AND**
- **ANY** of the following:
 - **ALL** of the following:
 - ◆ Chronic fecal incontinence, as indicated by the uncontrolled passage of fecal materials for a duration of at least 3 months; **AND**
 - ◆ Failure of dietary modifications, physical therapy, bowel management program, and medication; **OR**
 - Urinary retention or incomplete bladder emptying (including drug-induced retention) when sacral

nerve stimulation is considered as an alternative to intermittent self-catheterization; **OR**

- **ALL** of the following:

- ◆ Failure of behavioral modifications, physical therapy/biofeedback, and pharmacotherapy (e.g., anti-cholinergic or beta-agonist medications); **AND**

- ◆ **ANY** of the following:

- Neurogenic lower urinary tract dysfunction; **OR**
- Overactive bladder; **OR**
- Urinary symptoms for incomplete SCI without posterior rhizotomy; **OR**
- Urge incontinence; **OR**
- Urinary frequency; **OR**
- Urinary urgency; **OR**

- ◆ **Removal, revision, or replacement** of an existing neurostimulation device that is nonfunctioning, has a depleted battery, or is damaged (fractured leads or other damage).^{1,2,4,5}

Non-Indications

→ **Electrical neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Current pregnancy^{1,2,4,5}; **OR**

- ◆ Active infection^{1,2,4,5}; **OR**

- ◆ **Gastric pacing/gastric neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**¹⁻³:

- Current opioid use; **OR**
- Cannabinoid hyperemesis; **OR**
- Predominant symptom of gastroparesis is abdominal pain, bloating, or discomfort; **OR**
- Cyclic vomiting syndrome in absence of other criteria; **OR**
- Diabetes mellitus in absence of other criteria; **OR**
- Obesity in absence of other criteria; **OR**
- Eating disorder in absence of other criteria; **OR**
- Psychogenic vomiting in absence of other criteria; **OR**
- Functional dyspepsia in absence of other criteria; **OR**
- Congenital hypertrophic pyloric stenosis in absence of other criteria; **OR**

- ◆ **Peripheral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{6,7}:
 - This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.
- ◆ **Sacral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{4,5}:
 - Stress incontinence; **OR**
 - Urethral obstruction or stricture; **OR**
 - Benign prostatic hypertrophy; **OR**
 - Fecal incontinence that is associated with constipation–predominant defecatory pattern; **OR**
 - Fecal incontinence that is related to rectal intussusception.^{8,9}

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of gastric neurostimulator pulse generator
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open

Medical Evidence

Electrical nerve stimulation has been used to modulate pain, incontinence, vomiting, and other debilitating symptoms since the 1960s. At present, a range of devices exist to therapeutically stimulate the gastric, peripheral, and sacral nerves.

The American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) have published guidance around the use of electrical stimulation for gastroparesis. The ACG endorses the treatment of medically refractory gastroparesis with gastric electrical stimulation. Importantly, this is a conditional recommendation made with low-quality evidence. The AGA's 2022 clinical practice guidelines encouraged clinicians to consider electrical stimulation only for those patients with intractable and refractory nausea and vomiting, provided that they had no success with conventional therapy and were not taking opioids. These professional guidelines underscore the importance of appropriate patient selection. Gastric pacing remains an advanced therapy for patients who have exhausted other treatment options. A 2024 systemic review and meta-analysis by Saleem et al. examined a total of 730 patients with gastric stimulators. One year after implantation, patients saw a significantly improved gastrointestinal total symptom score (TSS), reduced frequency in vomiting episodes, improved gastric emptying study, and improved quality of life. The authors concluded that gastric electrical stimulation remains a treatment option for gastroparesis that is refractory to traditional treatment, acknowledging gastroparesis as a high-burden disease with an associated elevated mortality rate.¹⁻³

In 2024, the American Society of Interventional Pain Physicians (ASIPP) published evidence-based recommendations to guide the use of implanted peripheral nerve stimulators to manage chronic pain. Based on fair-quality evidence, they issued a recommendation of moderate strength for the use of peripheral stimulators in patients with chronic pain that is moderate or severe in nature, has failed two or more conventional treatments, and has successfully responded to a trial period with a test stimulation device. The authors note that the evidence base remains low-quality and heterogeneous, positing that this has impeded the field's ability to reach a definitive

consensus regarding use. In 2022, the American Society of Pain and Neuroscience (ASPN) published similar guidelines reviewing specific scenarios for peripheral nerve stimulation. All discussed scenarios received a recommendation of level B or C (“recommendable” or “neither recommendable nor inadvisable”). As in the ASIPP guidelines, the evidence base is not yet strong enough to make a robust recommendation for the safe, effective use of peripheral nerve stimulators. At present, this service is clinically unproven and, therefore, not medically necessary.^{6,7}

Sacral nerve stimulation provides bladder and bowel control when it is absent or impaired. The American Society of Colon and Rectal Surgeons (ASCRS) issued practice guidelines in 2023 to aid in the treatment of fecal incontinence. Sacral neuromodulation was felt to be a conditional recommendation, and the authors noted the relative dearth of knowledge around sacral nerve stimulation as compared to other techniques. In their review of the literature, sacral nerve stimulation offers at least a 50% improvement in symptoms for many patients. Sacral neuromodulation may confer greater efficacy than optimal medical therapy for certain patients. The American Urological Association (AUA) has also published guidance for the use of electrical stimulation among patients with urinary dysfunction. A variety of common urological problems, including overactive bladder and urge incontinence, are improved with sacral nerve stimulation when patients have failed traditional therapy. An exception to this is urinary retention, which does not require failure of conservative therapy if sacral nerve stimulation is considered as an alternative to intermittent self-catheterization.^{4,5}

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Review History		



Cohere Medical Policy - Gastric Pacing/Electrical Stimulation

Clinical Policy for Medical Necessity Review

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Policy Information:

Specialty Area: Gastroenterology/Urology/Musculoskeletal Care

Policy Name: Cohere Medical Policy - Gastric Pacing/Electrical Stimulation

Policy Number: CHP-025-2.1

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Gastric Pacing/Electrical Stimulation

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation or those that do not align with the provided clinical information—such as mismatched laterality, body part, or CPT code—may be denied due to a lack of medical necessity resulting from insufficient or inconsistent clinical information.
- When multiple diagnostic or therapeutic procedures are requested simultaneously or within the past 3 months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request.
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed.
 - How the results will impact patient management or treatment decisions.
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Description

Electrical stimulation is a treatment modality in which inappropriate or excessive neural activity is modulated using electrical impulses. These impulses are delivered by a surgically implanted device and target specific nerves. Gastric electrical stimulation (GES) involves the delivery of electrical pulses to the stomach wall in order to modulate the enteric nervous system and decrease symptoms of impaired gastric neural regulation. Electrical stimulation is delivered via two leads implanted in the smooth muscle of the stomach and connected to a subcutaneously implanted pulse generator.¹⁻³ Peripheral nerve stimulation (PNS) purports to treat acute and chronic pain affecting the lower back, extremities, trunk, head, and face. A neurostimulator device is implanted, and electrodes are placed near the affected peripheral nerves. Electrical stimulation can then be targeted to specific nerves.⁴⁻⁶ In sacral neurostimulation/neuromodulation (SNM), a neurostimulator device is positioned to deliver nonpainful electrical impulses to the sacral nerves, which control bowel, bladder, and pelvic floor function.^{1,2,7-9}

Medical Necessity Criteria

Indications

Electrical neurostimulation is considered appropriate if **ANY** of the following is **TRUE**:

- **Gastric electrical stimulation (GES)** is considered appropriate if **ALL** of the following are **TRUE**^{1,8,10}:
 - Documented confirmation of gastroparesis (gastric emptying delay with >10% tracer retention at 4 hours) on a 4-hour scintigraphic or breath test gastric emptying study^{8,11}; **AND**
 - Nausea or vomiting as the predominant symptom^{1,8}; **AND**
 - Other anatomic/organic causes have been excluded with upper endoscopy and selective imaging, if clinically indicated^{1,8}; **AND**
 - Failure of or intolerance to **ALL** of the following conservative measures:
 - Dietary modification (e.g., small particle diet)^{1,8}; **AND**
 - Over-the-counter (OTC) therapy^{1,8}; **AND**
 - Anti-emetics^{1,8}; **AND**
 - Prokinetics (e.g., erythromycin, domperidone, metoclopramide, and prucalopride)^{1,8}; **AND**
 - Conservative measures trialed for a duration of 1 year or more; **OR**
- **Sacral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**^{2,9}:
 - **ANY** of the following sacral nerve stimulation procedures:
 - Screening trial; **OR**
 - Permanent implantation after a successful stimulation trial as defined by **ALL** of the following:
 - Greater than or equal to 50% sustained reduction in symptoms compared to baseline; **AND**
 - For more than 48 hours; **AND**
 - **ANY** of the following symptoms:
 - Chronic fecal incontinence with **ALL** of the following:
 - Uncontrolled passage of fecal material for greater than or equal to 3 months; **AND**
 - Failure of **ALL** of the following:
 - Bowel management program; **AND**
 - Dietary modifications; **AND**
 - Medical management; **AND**
 - Physical therapy; **OR**

- Urinary retention or incomplete bladder emptying (including drug-induced retention) as an alternative to intermittent self-catheterization; **OR**
- Urinary voiding dysfunction with **ALL** of the following:
 - Symptoms affecting quality of life for greater than or equal to 6 months; **AND**
 - Failure of **ALL** of the following:
 - Behavioral modifications; **AND**
 - Physical therapy/biofeedback; **AND**
 - Pharmacotherapy (e.g., anti-cholinergic or beta-agonist medications); **AND**
 - **ANY** of the following symptoms:
 - Non-obstructive urinary retention; **OR**
 - Neurogenic lower urinary tract dysfunction; **OR**
 - Overactive bladder; **OR**
 - Urge incontinence; **OR**
 - Urinary frequency; **OR**
 - Urinary symptoms for incomplete spinal cord injury without posterior rhizotomy; **OR**
 - Urinary urgency; **OR**
- **Removal, revision, or replacement** of an existing neurostimulation device that is nonfunctioning, has a depleted battery, or is damaged (fractured leads or other damage).^{[1,2,8,9](#)}

Non-Indications

Electrical neurostimulation is not considered appropriate if **ANY** of the following is **TRUE**:

- Peripheral neurostimulation^{A.12,13}; **OR**
- Current pregnancy^{1,2,8,9}; **OR**
- Active infection^{1,2,8,9}; **OR**
- **Gastric pacing/gastric neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{1,8,10}:
 - Current opioid use; **OR**
 - Cannabinoid hyperemesis; **OR**
 - Predominant symptom of gastroparesis is abdominal pain, bloating, or discomfort; **OR**
 - As treatment for **ANY** of the following in the absence of other criteria:
 - Congenital hypertrophic pyloric stenosis; **OR**
 - Cyclic vomiting syndrome; **OR**
 - Diabetes mellitus; **OR**
 - Eating disorder; **OR**
 - Functional dyspepsia; **OR**
 - Obesity; **OR**
 - Psychogenic vomiting; **OR**
- **Sacral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{2,9}:
 - Benign prostatic hypertrophy; **OR**
 - Chronic constipation; **OR**
 - Chronic pelvic pain in the absence of other criteria; **OR**
 - Diabetes with peripheral nerve involvement; **OR**
 - Fecal incontinence associated with constipation-predominant defecatory pattern; **OR**
 - Fecal incontinence related to **ANY** of the following:
 - Anorectal malformation; **OR**
 - Peripheral neuropathy or complete spinal cord injury; **OR**
 - Rectal intussusception^{11,14,15}; **OR**
 - Multiple sclerosis; **OR**
 - Stress incontinence; **OR**
 - Urethral obstruction or stricture.

Definitions and Notes

^AEvidence is insufficient to determine that this service is a standard medical treatment. There is an absence of current, widely used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes, establishing the value of this service.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
64596	Insertion or replacement of percutaneous electrode

	array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
64999	Unlisted procedure, nervous system
L8680	Implantable neurostimulator electrode, each
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8681	Patient programmer, (external) for use with implantable programmable neurostimulator pulse generator, replacement only
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser

Medical Evidence

Gastric electrical stimulation (GES)

A 2024 systematic review and meta-analysis by Saleem et al. included 730 patients with gastric stimulators. One year after implantation, patients experienced a significantly improved gastrointestinal total symptom score (TSS), reduced vomiting frequency, improved gastric emptying study results, and enhanced quality of life. The authors concluded that gastric electrical stimulation remains a viable treatment option for gastroparesis refractory to traditional therapies, acknowledging that gastroparesis is a high-burden disease with a high mortality rate.¹⁰

Cassidy et al. (2024) reported long-term follow-up in 157 patients who underwent GES for medically refractory gastroparesis. The authors reported decreased severity of all nine gastroparesis symptoms evaluated at both 1-year and 5-year timepoints. Additionally, decreases were observed in prokinetic and antiemetic medication use and in gastroparesis-related hospitalizations, and patient satisfaction was high. Only five patients required explant of the device, one due to a pocket infection and four due to insufficient symptom relief. Overall, the authors concluded that GES can provide enduring symptom relief, reduce medication use, and decrease hospitalizations.³

Orsagh-Yentis et al. (2021) reported outcomes of GES in 85 pediatric patients (mean age, 15.8 years; range, 2-19 years). The authors reported post-implantation decreases in all individual symptoms measured, including vomiting frequency, vomiting severity, early satiety, bloating, postprandial fullness, and epigastric pain. Notably, feeding tube use decreased from 72.7% at baseline to 29.9% at final follow-up, and total parenteral nutrition (TPN) dependence decreased by more than half. Overall quality of life and health measures improved, and patient and family satisfaction with the procedure was high.¹⁶

Islam et al. (2016) reported outcomes in 97 children (mean age, 13.7 years; range, 2-19 years) with refractory gastroparesis who underwent GES. Patients had delayed gastric emptying on scintigraphy, a long duration of symptoms

(mean 3.5 years), previous and ongoing use of promotility, antiemetic, pain, and/or antireflux agents. A majority (66%) of patients reported at least one previous procedure, including fundoplication. Symptom improvement was reported in 66 patients, with improved symptom scores at 1, 6, and 12 months after implantation. Symptom recurrence and device removal were reported in 7 patients. The authors concluded that GES is safe and effective in pediatric patients with intractable gastroparesis.¹⁷

The American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) have published guidance around the use of electrical stimulation for gastroparesis. The 2025 AGA clinical practice guideline on management of gastroparesis contains 12 recommendations on diagnosis and treatment, including coverage of medical, surgical, and other therapies. Regarding gastroparesis refractory to medical therapy, the AGA recommends against routine use of GES. The comment associated with this conditional recommendation states that patients and providers who value potential improvement and symptom relief over the potential for adverse events may reasonably elect GES. The guidelines further note that GES should be used only in select patients with medically refractory gastroparesis and that patients should be informed that, while GES can improve nausea and vomiting, it is not expected to alleviate abdominal pain.¹¹ Similarly, the AGA's 2022 clinical practice guidelines encourage clinicians to consider electrical stimulation only for patients with intractable and refractory nausea and vomiting, provided that they had no success with conventional therapy and were not taking opioids. These professional guidelines underscore the importance of appropriate patient selection.¹⁸

Peripheral nerve stimulation (PNS)

Manchikanti et al. (2025) conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) examining the effectiveness of PNS for chronic pain management. All studies were evaluated according to five criteria: methodological limitations, consistency, indirectness, imprecision, and publication bias. Of the nine studies evaluated, seven were rated moderate and two low, with no studies meeting criteria for a high grade. In their assessment of the certainty of evidence, which included evaluation of study design, risk of bias, inconsistency, indirectness, imprecision, and publication bias, seven studies were found effective, and the overall certainty of evidence was rated as moderate. Overall, the authors classified the

evidence for PNS as level III (fair). Individually, the studies included in this meta-analysis reported moderate effect sizes and moderate strength of evidence across multiple pain indications, including migraine and low back pain. Limitations of the studies included: risk of bias, clinical and methodological heterogeneity, inconsistent data availability, small effect sizes, the absence of true placebo groups, high study withdrawal rates, and lack of long-term follow-up.⁶

The 2024 American Society of Interventional Pain Physicians (ASIPP) evidence-based clinical guideline on the use of implanted peripheral nerve stimulators to manage chronic pain includes a review of PNS research and recommendations for its use. The evidence on the use of peripheral stimulators in a patient with moderate or severe chronic pain who has failed two or more conventional treatments and has successfully responded to a trial period with a test stimulation device was rated as fair, supporting a moderate strength recommendation. The guideline notes that the evidence base remains low-quality and heterogeneous, suggesting that this has hindered the field's ability to reach a definitive consensus regarding appropriate use. The 2022 American Society of Pain and Neuroscience (ASPN) guidelines similarly review specific scenarios for peripheral nerve stimulation. All discussed scenarios have a recommendation of level B or C ("recommendable" or "neither recommendable nor inadvisable").^{12,13}

Sacral nerve stimulation

Amundson et al. (2025) conducted a systematic review and meta-analysis comparing the efficacy of sacral nerve stimulation/sacral neuromodulation (SNM) and implantable tibial neuromodulation (iTNM) in the management of overactive bladder (OAB). Their final analysis included 20 studies, with 1416 patients treated with SNM and 350 treated with iTNM. They reported no differences in treatment efficacy between SNM and iTNM, with similar reductions in urgency urinary incontinence, OAB, and incontinence episodes, and similar improvements in quality of life. Additionally, both devices had similarly low complication rates. The authors concluded that neuromodulation, whether via SNM or iTNM, is safe and effective for managing urinary complications.¹⁹

Faure et al. (2025) reported that SNM was successful in treating idiopathic overactive bladder (OAB) in four pediatric patients (mean age 8.5 years) and non-neurogenic urinary retention in three patients (mean age 16 years). All patients had unsuccessfully attempted conservative treatments, including urotherapy and anticholinergics, prior to SNM. Complications were minimal and included wound infection and device dysfunction, leading to surgical revision in two patients. The authors concluded that SNM is safe and effective in pediatric patients with refractory non-neurogenic vesico-sphincter disorders.²⁰

Besendörfer et al. (2024) reported a prospective trial investigating the efficacy of SNM in 15 pediatric patients (mean age, 8 years; range, 4–17 years) with refractory neuronal enteropathies. The authors reported improved defecation frequency in eight patients and improved fecal incontinence in nine patients. Notably, eight of the patients had Hirschsprung’s disease, which results in severe gastrointestinal motility dysfunction, with SNM successfully improving symptoms in seven of these. Findings were stable at 12-month follow-up. The authors concluded that SNM is a promising treatment for chronic constipation and fecal incontinence in pediatric patients.²¹

The 2024 American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guideline on the diagnosis and treatment of overactive bladder (OAB) comprises 33 statements that cover various treatment options, ranging from pharmacotherapy to indwelling catheters. The guidelines strongly recommend noninvasive treatments, including bladder training, fluid management, pelvic floor muscle therapy, transvaginal electrical stimulation, and pharmacotherapy prior to consideration of minimally invasive procedures. Minimally invasive procedures may include sacral neuromodulation, tibial nerve stimulation, and intradetrusor botulinum toxin injection. The guidelines note that these treatments have high success rates, durability, and patient satisfaction. Specifically, these treatments can decrease voiding frequency, nocturia, and the number of urgency and incontinence episodes.²²

The 2023 American Society of Colon and Rectal Surgeons (ASCRS) practice guideline on the treatment of fecal incontinence provides SNM with a

conditional recommendation due to the limited research on sacral nerve stimulation. The literature review notes that sacral nerve stimulation can result in at least a 50% improvement in symptoms for many patients. Moreover, for some patients, SNM may be more effective than optimal medical therapy. The American Urological Association (AUA) guideline on adult neurogenic lower urinary tract dysfunction contains guidance for the use of electrical stimulation. A variety of common urological problems, including overactive bladder and urge incontinence, improve with sacral nerve stimulation when patients have failed traditional therapy. An exception to this is urinary retention, which does not require failure of conservative therapy if sacral nerve stimulation is considered as an alternative to intermittent self-catheterization.²⁹

The 2017 International Continence Society (ICS) best practice statement on the use of sacral neuromodulation (SNM) states that SNM should not be considered a first-line therapy for either bowel or bladder disorders, and recommends initial trials of conservative measures, including physical and behavioral therapies. The statement goes on to recommend that SNM be offered to several groups of patients, including the following: those with treatment-resistant OAB regardless of the presence of incontinence; those with Fowler's syndrome, voiding dysfunction, and non-obstructive urinary retention; those with bothersome refractory fecal incontinence; and those with combined urinary and bowel symptoms. Limited evidence supports SNM for the following patients: those with interstitial cystitis (IC)/bladder pain syndrome (BPS), though it may be an option for these patients after appropriate assessment; and those with neurogenic lower urinary tract dysfunction (NLUTD). There is minimal evidence supporting the use of SNM in patients with non-IC/BPS pelvic pain, and the society does not recommend SNM for these patients. Notably, this best practice statement also contains recommendations for SNM in pediatric patients. The society recommends SNM in children who have failed an extended course of behavioral modification, biofeedback, and pharmacotherapy. The society also cautions that safety and effectiveness have not been established for pediatric patients and that implantation in pediatric patients may be more challenging.⁷

In their standardization document on the treatment of daytime urinary incontinence, the 2017 International Children's Continence Society (ICCS) notes that studies have demonstrated the efficacy of SNM in improving

neurogenic bladder dysfunction, with specific benefits reported in pediatric OAB, dysfunctional elimination syndrome, and Fowler syndrome. The society also recommends that SNM be adjunctive to standard urotherapy and pharmacotherapy, or as an alternative to these treatments in children unable to tolerate them.²³

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Policy Revision History/Information

Original Date: February 6, 2025		
Review History		
Version 2	02/12/2026	Annual review. CPT codes 64561 and 64581 added and criteria modified to accommodate sacral nerve stimulation trial. CPT codes 64555, 64575, 64596, 64999 added (no criteria changes required). Minor edits to medical necessity criteria for clarity and usability. Organized and expanded Medical Evidence section (added reference numbers 3-7, 11, 16-21, 23).
Version 2.1	04/21/2026	Added HCPCS codes L8680, L8688, L8681, C1767, C1778, C1787, and C1894 (no criteria changes required).



Cohere Medical Policy – Gastric Pacing/Electrical Stimulation

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: February 6, 2025

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Guideline Information:

Specialty Area: Gastroenterology/Urology/Disorders of the Musculoskeletal System

Guideline Name: Cohere Medical Policy - Gastric Pacing/Electrical Stimulation

Date of last literature review: 1/24/2025

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Gastric Pacing/Electrical Stimulation

Recommended Clinical Approach

Electrical stimulation is a treatment modality that modulates the inappropriate or excessive activity of nerves through the surgical implantation of a device that generates an electrical pulse to stimulate the nerves of a specific region. Several types of neurostimulators exist.

- Gastric electrical stimulation (GES) is an advanced treatment for gastroparesis, a condition that manifests as delayed movement of food from the stomach to the small intestine. This may result in chronic nausea, vomiting, abdominal pain, bloating, and nutritional deficiency. Although gastroparesis may be well-controlled through less invasive methods, including dietary modification and medical therapy, a small percentage of patients experience refractory gastroparesis that causes intractable nausea and vomiting. Among such patients, gastric electrical stimulation is indicated, wherein a neurostimulator device is surgically placed beneath the skin to direct electrical impulses to the smooth muscle of the stomach. For appropriately selected patients, this often confers an improvement in symptoms and an overall improved quality of life.
- More than one-fifth of adults in the United States suffer from chronic pain. Peripheral nerve stimulation is approved by the US Food & Drug Administration for the treatment of chronic pain affecting the lower back, extremities, trunk, head, and face. A neurostimulator device is implanted in the appropriate area, and electrodes are placed near the affected peripheral nerves (i.e., nerves located outside of the brain and spinal cord). It is reserved for patients who have not attained adequate pain control through conventional treatment. Although the evidence base is growing, there is not yet enough research to validate this tool as an effective, safe means to control pain. This service is clinically unproven and not medically necessary at this time.
- Fecal incontinence and urinary complications are the primary indications for sacral neurostimulation. The neurostimulator device is positioned to deliver electrical impulses to the sacral nerves, which

control bowel and bladder function. It is an advanced tool for patients who have failed conventional, conservative therapy. Patient outcomes and quality of life are improved among appropriately selected patients.

Medical Necessity Criteria

Indications

→ **Electrical neurostimulation** is considered appropriate if **ANY** of the following is **TRUE**:

◆ **Gastric electrical stimulation (GES)** is considered appropriate if **ALL** of the following are **TRUE**¹⁻³:

- Documented confirmation of gastroparesis (gastric emptying delay with >10% tracer retention at 4 hours) on a 4-hour scintigraphic gastric emptying test; **AND**
- Predominant symptom is nausea or vomiting; **AND**
- Other anatomic/organic cause for symptoms has been excluded with upper endoscopy and selective imaging, if clinically indicated; **AND**
- Failure of **ALL** of the following:
 - Dietary modification (adoption of a small particle diet); **AND**
 - Over-the-counter (OTC) therapy; **AND**
 - Anti-emetics; **AND**
 - Prokinetics; **OR**

◆ **Sacral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**^{4,5}:

- Successful stimulation trial/test period of sacral nerve stimulation with at least a 50% reduction in symptoms compared to baseline; **AND**
- **ANY** of the following:
 - **ALL** of the following:
 - ◆ Chronic fecal incontinence, as indicated by the uncontrolled passage of fecal materials for a duration of at least 3 months; **AND**
 - ◆ Failure of dietary modifications, physical therapy, bowel management program, and medication; **OR**
 - Urinary retention or incomplete bladder emptying (including drug-induced retention) when sacral

nerve stimulation is considered as an alternative to intermittent self-catheterization; **OR**

- **ALL** of the following:

- ◆ Failure of behavioral modifications, physical therapy/biofeedback, and pharmacotherapy (e.g., anti-cholinergic or beta-agonist medications); **AND**

- ◆ **ANY** of the following:

- Neurogenic lower urinary tract dysfunction; **OR**
- Overactive bladder; **OR**
- Urinary symptoms for incomplete SCI without posterior rhizotomy; **OR**
- Urge incontinence; **OR**
- Urinary frequency; **OR**
- Urinary urgency; **OR**

- ◆ **Removal, revision, or replacement** of an existing neurostimulation device that is nonfunctioning, has a depleted battery, or is damaged (fractured leads or other damage).^{1,2,4,5}

Non-Indications

→ **Electrical neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Current pregnancy^{1,2,4,5}; **OR**

- ◆ Active infection^{1,2,4,5}; **OR**

- ◆ **Gastric pacing/gastric neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**¹⁻³:

- Current opioid use; **OR**
- Cannabinoid hyperemesis; **OR**
- Predominant symptom of gastroparesis is abdominal pain, bloating, or discomfort; **OR**
- Cyclic vomiting syndrome in absence of other criteria; **OR**
- Diabetes mellitus in absence of other criteria; **OR**
- Obesity in absence of other criteria; **OR**
- Eating disorder in absence of other criteria; **OR**
- Psychogenic vomiting in absence of other criteria; **OR**
- Functional dyspepsia in absence of other criteria; **OR**
- Congenital hypertrophic pyloric stenosis in absence of other criteria; **OR**

- ◆ **Peripheral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{6,7}:
 - This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.
- ◆ **Sacral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{4,5}:
 - Stress incontinence; **OR**
 - Urethral obstruction or stricture; **OR**
 - Benign prostatic hypertrophy; **OR**
 - Fecal incontinence that is associated with constipation–predominant defecatory pattern; **OR**
 - Fecal incontinence that is related to rectal intussusception.^{8,9}

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of gastric neurostimulator pulse generator
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open

Medical Evidence

Electrical nerve stimulation has been used to modulate pain, incontinence, vomiting, and other debilitating symptoms since the 1960s. At present, a range of devices exist to therapeutically stimulate the gastric, peripheral, and sacral nerves.

The American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) have published guidance around the use of electrical stimulation for gastroparesis. The ACG endorses the treatment of medically refractory gastroparesis with gastric electrical stimulation. Importantly, this is a conditional recommendation made with low-quality evidence. The AGA's 2022 clinical practice guidelines encouraged clinicians to consider electrical stimulation only for those patients with intractable and refractory nausea and vomiting, provided that they had no success with conventional therapy and were not taking opioids. These professional guidelines underscore the importance of appropriate patient selection. Gastric pacing remains an advanced therapy for patients who have exhausted other treatment options. A 2024 systemic review and meta-analysis by Saleem et al. examined a total of 730 patients with gastric stimulators. One year after implantation, patients saw a significantly improved gastrointestinal total symptom score (TSS), reduced frequency in vomiting episodes, improved gastric emptying study, and improved quality of life. The authors concluded that gastric electrical stimulation remains a treatment option for gastroparesis that is refractory to traditional treatment, acknowledging gastroparesis as a high-burden disease with an associated elevated mortality rate.¹⁻³

In 2024, the American Society of Interventional Pain Physicians (ASIPP) published evidence-based recommendations to guide the use of implanted peripheral nerve stimulators to manage chronic pain. Based on fair-quality evidence, they issued a recommendation of moderate strength for the use of peripheral stimulators in patients with chronic pain that is moderate or severe in nature, has failed two or more conventional treatments, and has successfully responded to a trial period with a test stimulation device. The authors note that the evidence base remains low-quality and heterogeneous, positing that this has impeded the field's ability to reach a definitive

consensus regarding use. In 2022, the American Society of Pain and Neuroscience (ASPN) published similar guidelines reviewing specific scenarios for peripheral nerve stimulation. All discussed scenarios received a recommendation of level B or C (“recommendable” or “neither recommendable nor inadvisable”). As in the ASIPP guidelines, the evidence base is not yet strong enough to make a robust recommendation for the safe, effective use of peripheral nerve stimulators. At present, this service is clinically unproven and, therefore, not medically necessary.^{6,7}

Sacral nerve stimulation provides bladder and bowel control when it is absent or impaired. The American Society of Colon and Rectal Surgeons (ASCRS) issued practice guidelines in 2023 to aid in the treatment of fecal incontinence. Sacral neuromodulation was felt to be a conditional recommendation, and the authors noted the relative dearth of knowledge around sacral nerve stimulation as compared to other techniques. In their review of the literature, sacral nerve stimulation offers at least a 50% improvement in symptoms for many patients. Sacral neuromodulation may confer greater efficacy than optimal medical therapy for certain patients. The American Urological Association (AUA) has also published guidance for the use of electrical stimulation among patients with urinary dysfunction. A variety of common urological problems, including overactive bladder and urge incontinence, are improved with sacral nerve stimulation when patients have failed traditional therapy. An exception to this is urinary retention, which does not require failure of conservative therapy if sacral nerve stimulation is considered as an alternative to intermittent self-catheterization.^{4,5}

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Clinical Guideline Revision History/Information

Original Date: February 6, 2025		
Review History		



Cohere Medicare Advantage Policy – Gastric Pacing/Electrical Stimulation

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: February 6, 2025

Important Notices

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Guideline Information:

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Medical Necessity Criteria

Service: Gastric Pacing/Electrical Stimulation

Benefit Category

Prosthetic devices.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁵

- [National Coverage Determination \(NCD\) 160.7: Electrical Nerve Stimulators](#)
- [National Coverage Determination \(NCD\) 230.18: Sacral Nerve Stimulation for Urinary Incontinence](#)
- [Local Coverage Determination \(LCD\) L39543: Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence](#)
- [Local Coverage Determination \(LCD\) L34328: Peripheral Nerve Stimulation](#)
- [Local Coverage Determination \(LCD\) L37360: Peripheral Nerve Stimulation](#)

Recommended Clinical Approach

Electrical stimulation is a treatment modality that modulates the inappropriate or excessive activity of nerves through the surgical implantation of a device that generates an electrical pulse to stimulate the nerves of a specific region. Several types of neurostimulators exist.

- Gastric electrical stimulation (GES) is an advanced treatment for gastroparesis, a condition that manifests as delayed movement of food from the stomach to the small intestine. This may result in chronic nausea, vomiting, abdominal pain, bloating, and nutritional deficiency. Although gastroparesis may be well-controlled through less invasive methods, including dietary modification and medical therapy, a small percentage of patients experience refractory gastroparesis that causes

intractable nausea and vomiting. Among such patients, gastric electrical stimulation is indicated, wherein a neurostimulator device is surgically placed beneath the skin to direct electrical impulses to the smooth muscle of the stomach. For appropriately selected patients, this often confers an improvement in symptoms and an overall improved quality of life.^{6,7}

- More than one-fifth of adults in the United States suffer from chronic pain.⁸ Peripheral nerve stimulation is approved by the US Food & Drug Administration for the treatment of chronic pain affecting the lower back, extremities, trunk, head, and face. A neurostimulator device is implanted in the appropriate area, and electrodes are placed near the affected peripheral nerves (i.e., nerves located outside of the brain and spinal cord). It is reserved for patients who have not attained adequate pain control through conventional treatment.
- Fecal incontinence and urinary complications are the primary indications for sacral neurostimulation. The neurostimulator device is positioned to deliver electrical impulses to the sacral nerves, which control bowel and bladder function. It is an advanced tool for patients who have failed conventional, conservative therapy. Patient outcomes and quality of life are improved among appropriately selected patients.^{6,7,9,10}

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of electrical stimulation. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Device-associated risks are possible with the implantation of nerve stimulators. These complications include infection, pain at the stimulation site, erosion of the device through the skin or stomach wall, excessive bleeding, and inadequate treatment of symptoms.
- Risks with inappropriate surgical procedures include infection, bleeding, injury to neurovascular structures, lead migration, anesthetic risk, and the need for repeat or additional procedures. If a patient has an inappropriate surgical procedure, this can lead to additional

complications, necessitating further invasive management; therefore, careful patient selection is in the patient's best interest.

- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The potential clinical benefits of using these criteria include:

- Nerve stimulators may offer symptom relief for patients who have exhausted other treatment options, including patients with intractable vomiting or recurrent incontinence. Non-opioid treatment of chronic pain may be possible with peripheral nerve stimulators.
- As compared to traditional treatment, including major procedures such as urostomy/colostomy formation for chronic incontinence, nerve stimulators are relatively less invasive and less expensive. Minimally invasive procedures confer a better patient safety profile and tend to require a shorter recovery period and a minimal (or eliminated) hospital stay.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Electrical neurostimulation** is considered appropriate if **ANY** of the following is **TRUE**:

- ◆ **Gastric electrical stimulation (GES)** is considered appropriate if **ALL** of the following are true:

- Documented confirmation of gastroparesis (gastric emptying delay with >10% tracer retention at 4 hours) on a 4-hour scintigraphic gastric emptying test^{6,9}; **AND**
 - Predominant symptom is nausea or vomiting^{6,9}; **AND**
 - Other anatomic/organic cause for symptoms has been excluded with upper endoscopy and selective imaging, if clinically indicated^{6,9}; **AND**
 - Failure of **ALL** of the following:
 - Dietary modification (adoption of a small particle diet)^{6,9}; **AND**
 - Over-the-counter (OTC) therapy^{6,9}; **AND**
 - Anti-emetics^{6,9}; **AND**
 - Prokinetics^{6,9}; **OR**
- ◆ **Peripheral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**:
- Chronic, severe pain for at least 3 months; **AND**
 - Failure of less invasive treatment modalities and medications^{14,5}; **AND**
 - Appropriate surgical candidate (no infection or relevant medical risks)^{14,5}; **AND**
 - Appropriate proper patient education, discussion and disclosure of risks and benefits^{14,5}; **AND**
 - No active substance abuse^{14,5}; **AND**
 - Formal psychological screening by a mental health professional^{14,5}; **AND**
 - Successful stimulation trial with greater than or equal to 50% reduction in pain intensity or 50% reduction in analgesic use before permanent implantation^{14,5}; **OR**
- ◆ **Sacral nerve stimulation** is considered appropriate if **ALL** of the following are true:
- **ANY** of the following:
 - Urinary urge incontinence^{2,3}; **OR**
 - Urinary frequency syndrome^{2,3}; **OR**
 - Urinary retention^{2,3}; **OR**
 - Chronic fecal incontinence with greater than 2 incontinent episodes on average per week for a duration of more than 6 months³; **AND**

- Failure or intolerance of conventional therapy (behavioral, pharmacologic, dietary, or surgical corrective therapy)^{2,3}; **AND**
 - Appropriate surgical candidate (no infection or relevant medical risks)^{2,3}; **AND**
 - Ability to record voiding diary data such that clinical results of the implant procedure may be properly evaluated^{2,3}; **AND**
 - Successful stimulation trial with greater than or equal to 50% sustained (more than 48 hours) reduction in symptoms^{2,3}; **OR**
- ◆ **Removal, revision, or replacement** of an existing neurostimulation device that is nonfunctioning, has a depleted battery, or is damaged (fractured leads or other damage).¹⁻⁷

Non-Indications

→ **Electrical neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ **Gastric pacing/gastric neurostimulation** is not considered appropriate if **ANY** of the following is true:
- Current opioid use^{6,9}; **OR**
 - Cannabinoid hyperemesis^{6,9}; **OR**
 - Predominant symptom of gastroparesis is abdominal pain, bloating, or discomfort^{6,9}; **OR**
 - Cyclic vomiting syndrome in absence of other criteria^{6,9}; **OR**
 - Diabetes mellitus in absence of other criteria^{6,9}; **OR**
 - Obesity in absence of other criteria^{6,9}; **OR**
 - Eating disorder in absence of other criteria^{6,9}; **OR**
 - Psychogenic vomiting in absence of other criteria^{6,9}; **OR**
 - Functional dyspepsia in absence of other criteria^{6,9}; **OR**
 - Congenital hypertrophic pyloric stenosis in absence of other criteria^{6,9}; **OR**
- ◆ **Peripheral neurostimulation** is not considered appropriate if **ANY** of the following is true:
- Fibromyalgia^{1,4,5}; **OR**
 - Phantom limb pain^{1,4,5}; **OR**
 - Diffuse polyneuropathy^{1,4,5}; **OR**
 - Nociceptive pain in trunk or lower back^{1,4,5}; **OR**
 - Angina pectoris^{1,4,5}; **OR**

- ◆ **Sacral neurostimulation** is not considered appropriate if **ANY** of the following is true:
- Stress incontinence^{2,3}; **OR**
 - Urethral obstruction or stricture^{2,3}; **OR**
 - Diabetes with peripheral nerve involvement^{2,3}; **OR**
 - Multiple sclerosis^{2,3}; **OR**
 - Benign prostatic hypertrophy^{2,3}; **OR**
 - Chronic constipation^{2,3}; **OR**
 - Fecal incontinence that is related to rectal intussusception^{14,15}; **OR**
 - Chronic pelvic pain in the absence of other criteria^{2,3}; **OR**
 - Fecal incontinence that is related to anorectal malformation^{2,3}; **OR**
 - Fecal incontinence that is related to peripheral neuropathy or complete spinal cord injury.^{2,3}

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of gastric neurostimulator pulse generator
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Electrical nerve stimulation has been used to modulate pain, incontinence, vomiting, and other debilitating symptoms since the 1960s. At present, a range of devices exist to therapeutically stimulate the gastric, peripheral, and sacral nerves.

The American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) have published guidance around the use of electrical stimulation for gastroparesis. The ACG endorses the treatment of medically refractory gastroparesis with gastric electrical stimulation. Importantly, this is a conditional recommendation made with low-quality evidence.⁶ The AGA's 2022 clinical practice guidelines encouraged clinicians to consider electrical stimulation only for those patients with intractable and refractory nausea and vomiting, provided that they had no success with conventional therapy and were not taking opioids. These professional guidelines underscore the importance of appropriate patient selection.⁹ Gastric pacing remains an advanced therapy for patients who have exhausted other treatment options. A 2024 systemic review and meta-analysis by Saleem et al. examined a total of 730 patients with gastric stimulators. At one year following implantation, patients saw a significantly improved gastrointestinal total symptom score (TSS), reduced frequency in vomiting episodes, improved gastric emptying study, and improved quality of life. The authors concluded that gastric electrical stimulation remains a treatment option for gastroparesis that is refractory to traditional treatment, acknowledging gastroparesis as a high-burden disease with an associated elevated mortality rate.¹¹

In 2024, the American Society of Interventional Pain Physicians (ASIPP) published evidence-based recommendations to guide the use of implanted peripheral nerve stimulators to manage chronic pain. Based on fair-quality evidence, they issued a recommendation of moderate strength for the use of peripheral stimulators in patients with chronic pain that is moderate or severe in nature, has failed two or more conventional treatments, and has successfully responded to a trial period with a test stimulation device. The authors note that the evidence base remains low-quality and heterogeneous, positing that this has impeded the field's ability to reach a definitive

consensus regarding appropriate use. In 2022, the American Society of Pain and Neuroscience (ASPN) published similar guidelines reviewing specific scenarios for peripheral nerve stimulation. All discussed scenarios received a recommendation of level B or C (“recommendable” or “neither recommendable nor inadvisable”).¹²⁻¹³

Sacral nerve stimulation provides bladder and bowel control when it is absent or impaired. The American Society of Colon and Rectal Surgeons (ASCRS) issued practice guidelines in 2023 to aid in the treatment of fecal incontinence. Sacral neuromodulation was felt to be a conditional recommendation, and the authors noted the relative dearth of knowledge around sacral nerve stimulation as compared to other techniques. In their review of the literature, sacral nerve stimulation offers at least a 50% improvement in symptoms for many patients. Sacral neuromodulation may confer greater efficacy than optimal medical therapy for certain patients. The American Urological Association (AUA) has also published guidance for the use of electrical stimulation among patients with urinary dysfunction. A variety of common urological problems, including overactive bladder and urge incontinence, are improved with sacral nerve stimulation when patients have failed traditional therapy. An exception to this is urinary retention, which does not require failure of conservative therapy if sacral nerve stimulation is considered as an alternative to intermittent self-catheterization.^{7,10}

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Clinical Guideline Revision History/Information

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Cohere Medicare Advantage Policy – Gastric Pacing/Electrical Stimulation

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Musculoskeletal Care / Gastroenterology / Urology

Policy Name: Cohere Medicare Advantage Policy - Gastric Pacing/Electrical Stimulation

Policy Number: CHP-021-2.2

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Gastric Pacing/Electrical Stimulation

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁸

- [National Coverage Determination \(NCD\). Electrical nerve stimulators \(160.7\)](#)
- [National Coverage Determination \(NCD\). Sacral nerve stimulation for urinary incontinence \(230.18\)](#)
 - [Billing and Coding: Sacral nerve stimulation for urinary and fecal incontinence \(A53359\)](#)
 - [Billing and Coding: Sacral nerve stimulation for urinary and fecal incontinence \(A55835\)](#)
- [Local Coverage Determination \(LCD\). Peripheral nerve stimulation \(L34328\)](#)
 - [Billing and Coding: Peripheral Nerve Stimulation \(A55530\)](#)
- [Local Coverage Determination \(LCD\). Sacral nerve stimulation for the treatment of urinary and fecal incontinence \(L39543\)](#)
 - [Billing and Coding: Sacral nerve stimulation for the treatment of urinary and fecal incontinence \(A59332\)](#)

Description

Electrical stimulation is a treatment modality in which inappropriate or excessive neural activity is modulated using electrical impulses. These impulses are delivered by a surgically implanted device and target specific nerves. Gastric electrical stimulation (GES) involves the delivery of electrical pulses to the stomach wall in order to modulate the enteric nervous system and decrease symptoms of impaired gastric neural regulation. Electrical stimulation is delivered via two leads implanted in the smooth muscle of the stomach and connected to a subcutaneously implanted pulse generator.⁹⁻¹¹

Peripheral nerve stimulation (PNS) is a United States Food & Drug Administration-authorized treatment for acute and chronic pain affecting the lower back, extremities, trunk, head, and face. A neurostimulator device is implanted, and electrodes are placed near the specific affected peripheral nerves.^{5,12-14} In sacral neurostimulation/neuromodulation (SNM), a neurostimulator device is positioned to deliver nonpainful electrical impulses to the sacral nerves, which control bowel, bladder, and pelvic floor function.^{7,9,10,15-17}

Medical Necessity Criteria

Indications

Electrical neurostimulation is considered appropriate if **ANY** of the following is **TRUE**:

- **Gastric electrical stimulation (GES)** is considered appropriate if **ALL** of the following are **TRUE**:
 - Documented confirmation of gastroparesis (gastric emptying delay with greater than 10% tracer retention at 4 hours) on a 4-hour scintigraphic or breath test gastric emptying study^{9,16,18}; **AND**
 - Nausea or vomiting as the predominant symptom^{9,16}; **AND**
 - Other anatomic/organic causes have been excluded with upper endoscopy and selective imaging, if indicated^{9,16}; **AND**
 - Failure of or intolerance to **ALL** of the following conservative measures:
 - Dietary modification (e.g., small particle diet)^{9,16}; **AND**
 - Over-the-counter (OTC) therapy^{9,16}; **AND**
 - Anti-emetics^{9,16}; **AND**
 - Prokinetics (e.g., erythromycin, domperidone, metoclopramide, and prucalopride)^{9,16}; **AND**
 - Conservative measures trialed for a duration of 1 year or more; **OR**
- **Peripheral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**^{5,12,14}:
 - Appropriate proper patient education, discussion, and disclosure of risks and benefits⁵; **AND**
 - Appropriate surgical candidate (i.e., no infection or relevant medical risks)⁵; **AND**
 - Chronic, severe pain for at least 3 months; **AND**
 - Failure of less invasive treatment modalities and medications^{5,12}; **AND**
 - Formal psychological screening by a mental health professional⁵; **AND**
 - No active substance abuse⁵; **AND**
 - Successful stimulation trial as defined by greater than or equal to 50% reduction in pain intensity; **OR**

- **Sacral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**^{2,7}:
 - **ANY** of the following symptoms:
 - Chronic fecal incontinence with greater than two incontinent episodes on average per week for a duration of more than 6 months^{2,7}; **OR**
 - Nonobstructive urinary retention^{2,7}; **OR**
 - Urinary urge incontinence^{2,7}; **OR**
 - Urinary frequency syndrome^{2,7}; **AND**
 - Ability to record voiding diary data such that clinical results of the implant procedure may be properly evaluated^{2,7}; **AND**
 - Appropriate surgical candidate (no infection or relevant medical risks)^{2,7}; **AND**
 - Failure or intolerance of conventional therapy (behavioral, pharmacologic, dietary, or surgical corrective therapy)^{2,7}; **AND**
 - **ANY** of the following sacral nerve stimulation procedures:
 - Screening trial; **OR**
 - Permanent implantation after a successful stimulation trial as defined by **ALL** of the following:
 - Greater than or equal to 50% sustained reduction in symptoms^{2,7}; **AND**
 - For greater than 48 hours; **OR**
- **Removal, revision, or replacement** of an existing neurostimulation device that is nonfunctioning, has a depleted battery, or is damaged (fractured leads or other damage).¹⁻⁸

Non-Indications

Electrical neurostimulation is not considered appropriate if **ANY** of the following is **TRUE**:

- **Gastric pacing/gastric neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{9,16}:
 - Current opioid use; **OR**
 - Cannabinoid hyperemesis; **OR**
 - Predominant symptom of gastroparesis is abdominal pain, bloating, or discomfort; **OR**
 - As treatment for **ANY** of the following in the absence of other criteria:
 - Congenital hypertrophic pyloric stenosis; **OR**
 - Cyclic vomiting syndrome; **OR**
 - Diabetes mellitus; **OR**
 - Eating disorder; **OR**
 - Functional dyspepsia; **OR**
 - Obesity; **OR**
 - Psychogenic vomiting; **OR**
- **Peripheral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{5,14}:
 - Angina pectoris; **OR**
 - Diffuse polyneuropathy; **OR**
 - Fibromyalgia; **OR**
 - Nociceptive pain in trunk or lower back; **OR**
 - Phantom limb pain; **OR**
- **Sacral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{2,7}:
 - Benign prostatic hypertrophy; **OR**
 - Chronic constipation; **OR**
 - Chronic pelvic pain in the absence of other criteria; **OR**
 - Diabetes with peripheral nerve involvement; **OR**
 - Fecal incontinence related to **ANY** of the following¹⁸⁻²⁰:
 - Rectal intussusception; **OR**
 - Anorectal malformation; **OR**
 - Peripheral neuropathy or complete spinal cord injury; **OR**
 - Multiple sclerosis; **OR**
 - Stress incontinence; **OR**
 - Urethral obstruction or stricture.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial

	electrode array
64999	Unlisted procedure, nervous system
L8680	Implantable neurostimulator electrode, each
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8681	Patient programmer, (external) for use with implantable programmable neurostimulator pulse generator, replacement only
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for electrical neurostimulation may include:

- Adverse effects from delayed or denied treatment, such as continued and worsening nausea, vomiting, pain, or incontinence.^{[21-23](#)} These symptoms may lead to reductions in quality of life and downstream effects, including impaired nutritional status, increased need for nutritional supplementation, and increased use of healthcare services.^{[21](#)}
- Device-associated risks are possible with the implantation of nerve stimulators. These complications include infection, pain at the stimulation site, erosion of the device through the skin or stomach wall, excessive bleeding, and inadequate treatment of symptoms.^{[11,15,21-24](#)}
- Risks with inappropriate surgical procedures include infection, bleeding, injury to neurovascular structures, lead migration, anesthetic risk, and the need for repeat or additional procedures.^{[11,15,21-24](#)}
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for electrical neurostimulation may include:

- Improved patient selection for electrical neurostimulation, resulting in better long-term outcomes. Ideal candidates for gastric stimulation should have a predominance of nausea/vomiting symptoms and be free from narcotic use prior to electrode implantation.^{[21](#)}
- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients with active opioid use treated with gastric stimulation

may experience poor, inconsistent, or short-lived relief from their gastric symptoms, which may be driven or exacerbated by the opioid use.²⁵ This may lead to downstream increases in opioid use and further worsening of symptoms.

- Nerve stimulators may offer symptom relief for patients who have exhausted other treatment options, including patients with intractable vomiting or recurrent incontinence. Non-opioid treatment of chronic pain may be possible with peripheral nerve stimulators.
- Compared to traditional treatments, including major surgical procedures such as urostomy/colostomy formation for chronic incontinence, nerve stimulators are less invasive and less expensive. Minimally invasive procedures generally offer a better patient safety profile, a shorter recovery period, and a minimal (or sometimes eliminated) hospital stay.
- Enhanced overall patient satisfaction and healthcare experience.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Gastric electrical stimulation (GES)

A 2024 systematic review and meta-analysis by Saleem et al. included 730 patients with gastric stimulators. One year after implantation, patients experienced a significantly improved gastrointestinal total symptom score (TSS), reduced vomiting frequency, improved gastric emptying study results, and enhanced quality of life. The authors concluded that gastric electrical stimulation remains a viable treatment option for gastroparesis refractory to traditional therapies, acknowledging that gastroparesis is a high-burden disease with a high mortality rate.²⁶

Cassidy et al. (2024) reported long-term follow-up in 157 patients who underwent GES for medically refractory gastroparesis. The authors reported decreased severity of all nine gastroparesis symptoms evaluated at both 1-year and 5-year timepoints. Additionally, decreases were observed in prokinetic and antiemetic medication use and in gastroparesis-related hospitalizations, and patient satisfaction was high. Only five patients required explant of the device, one due to a pocket infection and four due to insufficient symptom relief. Overall, the authors concluded that GES can provide enduring symptom relief, medication-use reduction, and hospitalization decreases.²⁷

Orsagh-Yentis et al. (2021) reported outcomes of GES in 85 pediatric patients (mean age, 15.8 years; range, 2–19 years). The authors reported post-implantation decreases in all individual symptoms measured, including vomiting frequency, vomiting severity, early satiety, bloating, postprandial fullness, and epigastric pain. Notably, feeding tube use decreased from 72.7% at baseline to 29.9% at final follow-up, and total parenteral nutrition (TPN) dependence decreased by more than half. Overall quality of life and health measures improved, and patient and family satisfaction with the procedure was high.²⁷

Islam et al. (2016) reported outcomes in 97 children (mean age, 13.7 years; range, 2–19 years) with refractory gastroparesis who underwent GES. Patients

had delayed gastric emptying on scintigraphy, a long duration of symptoms (mean 3.5 years), previous and ongoing use of promotility, antiemetic, pain, and/or antireflux agents. A majority (66%) of patients reported at least one previous procedure, including fundoplication. Symptom improvement was reported in 66 patients, with improved symptom scores at 1, 6, and 12 months after implantation. Symptom recurrence and device removal were reported in seven patients. The authors concluded that GES is safe and effective in pediatric patients with intractable gastroparesis.²⁸

The American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) have published guidance on the use of electrical stimulation for gastroparesis. The 2025 AGA clinical practice guideline on management of gastroparesis contains 12 recommendations on diagnosis and treatment, including coverage of medical, surgical, and other therapies. Regarding gastroparesis refractory to medical therapy, the AGA recommends against routine use of GES. The comment associated with this conditional recommendation states that patients and providers who value potential improvement and symptom relief over the potential for adverse events may reasonably elect GES. The guidelines further note that GES should be used only in select patients with medically refractory gastroparesis and that patients should be informed that, while GES can improve nausea and vomiting, it is not expected to alleviate abdominal pain.¹⁸ Similarly, the AGA's 2022 clinical practice guidelines encourage clinicians to consider electrical stimulation only for patients with intractable and refractory nausea and vomiting, provided that they had no success with conventional therapy and were not taking opioids. These professional guidelines underscore the importance of appropriate patient selection.²⁹

Peripheral nerve stimulation (PNS)

Manchikanti et al. (2025) conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) examining the effectiveness of PNS for chronic pain management. Their final analysis included nine studies. At 1-month follow-up, significantly fewer patients treated with PNS reported pain and functional disability compared to control group patients. These effects were maintained at both the 3-month and 12-month follow-ups, indicating that PNS may have a meaningful long-term impact on pain and daily functioning. The authors concluded that the overall evidence supporting PNS

for pain treatment was level III (fair), with moderate certainty and moderate strength of evidence. The authors further outlined seven criteria to guide patient selection for PNS. These criteria included: documented function-limiting moderate to severe pain (average pain score greater than or equal to 5) that has persisted for at least 3 months; documented failure of less invasive treatment for at least 4 weeks; absence of surgical contraindications; completion of patient education; no substance abuse; psychological evaluation; and successful trial stimulation.¹⁴

D'Souza et al. (2025) reported a broader systematic review and meta-analysis of studies examining the use of PNS for chronic pain. Their final analysis included both RCTs and observational studies, comprising 106 studies and 9272 patients. The authors reported that PNS decreased pain intensity at all time points evaluated: 3, 6, 12, and 24 months. The authors concluded that implantable PNS provides enduring and clinically meaningful relief of chronic pain that is refractory to conventional therapies. The authors also noted that these effects did not differ by study type, suggesting that the pain-reducing effects of PNS are not limited to patients meeting narrow clinical trial selection criteria.³⁰

Peer-reviewed studies on the use of PNS in pediatric patients are limited. A 2024 case series reported the use of ultrasound-guided suprascapular nerve PNS in the treatment of cancer-related pain in two pediatric patients (ages 16 years and 17 years). Both patients had trialed medical pain relief and either did not tolerate or were unable to attempt other pain relief strategies. The average pain score of one patient decreased from 10 at baseline to 7 in the first week following PNS, and then to 4 at 60-day follow-up. The other patient's average pain score decreased from 8 at baseline to 5 at 30-day follow-up, further decreasing to 3 at 60-day follow-up. The authors concluded that PNS can be safe and effective in decreasing cancer-related pain in pediatric patients.³¹

Similarly, Garya et al. (2023) reported that PNS successfully decreased pediatric neuropathic leg pain in a 15-year-old patient. Two years after an accident, the patient reported significant thigh and knee pain despite conservative treatments including physical therapy, mobility exercises, use of a sleeve/brace, and pain medication. Two months following implantation of

the stimulator, the patient reported significant pain relief and improved quality of life. The authors concluded that PNS holds promise as a treatment option for pediatric neuropathic pain, cautioning that it may not be appropriate for all pediatric patients. Specifically, the authors noted that PNS may be more suitable for adolescent patients than for younger pediatric patients. Additionally, the authors noted that cognitive delays that prevent a patient from expressing adverse effects may disqualify a patient from PNS, and that young children (under 10 years of age) may be unable to handle and care for the device.²⁴

The 2025 American Society of Pain and Neuroscience (ASPN) consensus guideline for the use of PNS in the treatment of chronic pain and neurological diseases reviews the peer-reviewed research on PNS and presents 18 consensus statements on its efficacy and optimal use. Consensus guideline statements include: anesthetic nerve blocks, while potentially useful in determining patient anatomy and identifying stimulation target nerves, should not be considered prognostic in predicting a response to PNS; stimulation platform (external, implantable, or hybrid) should be determined through shared decision making between the patient and the provider; consideration of future magnetic resonance imaging (MRI) should inform platform selection; and high level evidence supports the use of PNS in patients with chronic pain.¹²

The 2025 ASPN consensus guideline on the use of 60-day PNS cites research demonstrating that traditional 10–14 day stimulation trial periods may not be adequate for a significant proportion of patients. These relatively short trial periods may both falsely identify patients with early yet transient responses to stimulation as good candidates for PNS and those with delayed yet enduring responses as bad candidates. The guidelines contain strong recommendations for a 60-day PNS in the treatment of the following pain etiologies: chronic low back pain (LBP) with central contributions, postoperative refractory knee pain, phantom and residual limb pain, and postamputation pain. Moderate recommendations are issued for: chronic LBP, chronic LBP after facet radiofrequency ablation, post-operative refractory foot and ankle pain, neuropathic pain, occipital neuralgia, inoperable shoulder pain, and post-operative refractory shoulder pain.¹³

The 2024 American Society of Interventional Pain Physicians (ASIPP) evidence-based clinical guidelines on the use of implanted peripheral nerve stimulators to manage chronic pain include a review of PNS research and recommendations for its use. Based on fair-quality evidence, a moderate-strength recommendation supports the use of peripheral stimulators in a patient with moderate or severe chronic pain that has failed two or more conventional treatments and has successfully responded to a trial period with a test stimulation device. The authors note that the evidence base remains low-quality and heterogeneous, suggesting that this has hindered the field's ability to reach a definitive consensus regarding appropriate use. The 2022 American Society of Pain and Neuroscience (ASPN) guidelines similarly review specific scenarios for peripheral nerve stimulation. All discussed scenarios have a recommendation of level B or C ("recommendable" or "neither recommendable nor inadvisable").^{[32,33](#)}

Sacral nerve stimulation

Amundson et al. (2025) conducted a systematic review and meta-analysis comparing the efficacy of sacral nerve stimulation/sacral neuromodulation (SNM) and implantable tibial neuromodulation (iTNM) in the management of overactive bladder (OAB). Their final analysis included 20 studies, with 1416 patients treated with SNM and 350 treated with iTNM. They reported no differences in treatment efficacy between SNM and iTNM, with similar reductions in urgency, OAB, and incontinence episodes, and similar improvements in quality of life. Additionally, both devices had similarly low complication rates. The authors concluded that neuromodulation, whether via SNM or iTNM, is safe and effective for managing urinary complications.^{[34](#)}

Faure et al. (2025) reported that SNM was successful in treating idiopathic overactive bladder (OAB) in four pediatric patients (mean age 8.5 years) and non-neurogenic urinary retention in three patients (mean age 16 years). All patients had unsuccessfully attempted conservative treatments, including urotherapy and anticholinergics, prior to SNM. Complications were minimal and included wound infection and device dysfunction, leading to surgical revision in two patients. The authors concluded that SNM is safe and effective in pediatric patients with refractory non-neurogenic vesico-sphincter disorders.^{[35](#)}

Besendörfer et al. (2024) reported a prospective trial investigating the efficacy of SNM in 15 pediatric patients (mean age, 8 years; range, 4-17 years) with refractory neuronal enteropathies. The authors reported improved defecation frequency in eight patients and improved fecal incontinence in nine patients. Notably, eight of the patients had Hirschsprung's disease, which results in severe gastrointestinal motility dysfunction, with SNM successfully improving symptoms in seven of these. Findings were stable at 12-month follow-up. The authors concluded that SNM is a promising treatment for chronic constipation and fecal incontinence in pediatric patients.³⁶

The 2024 American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guideline on the diagnosis and treatment of OAB comprises 33 statements that cover various treatment options, ranging from pharmacotherapy to indwelling catheters. The guidelines strongly recommend noninvasive treatments, including bladder training, fluid management, pelvic floor muscle therapy, transvaginal electrical stimulation, and pharmacotherapy prior to consideration of minimally invasive procedures. Minimally invasive procedures may include sacral neuromodulation, tibial nerve stimulation, and intradetrusor botulinum toxin injection. The guidelines note that these treatments have high success rates, durability, and patient satisfaction. Specifically, these treatments can decrease voiding frequency, nocturia, and the number of urgency and incontinence episodes.³⁷

The 2023 American Society of Colon and Rectal Surgeons (ASCRS) practice guideline on the treatment of fecal incontinence provides SNM with a conditional recommendation due to the limited research on sacral nerve stimulation. The literature review notes that sacral nerve stimulation can result in at least a 50% improvement in symptoms for many patients. Moreover, for some patients, SNM may be more effective than optimal medical therapy. The American Urological Association (AUA) guideline on adult neurogenic lower urinary tract dysfunction contains guidance for the use of electrical stimulation. A variety of common urological problems, including overactive bladder and urge incontinence, improve with sacral nerve stimulation when patients have failed traditional therapy. An exception to this is urinary retention, which does not require failure of conservative

therapy if sacral nerve stimulation is considered as an alternative to intermittent self-catheterization.^{10,17}

The 2017 International Continence Society (ICS) best practice statement on the use of sacral neuromodulation (SNM) states that SNM should not be considered a first-line therapy for either bowel or bladder disorders, and recommends initial trials of conservative measures, including physical and behavioral therapies. The statement goes on to recommend that SNM be offered to several groups of patients including: those with treatment-resistant OAB regardless of the presence of incontinence; those with Fowler's syndrome, voiding dysfunction, and non-obstructive urinary retention; those with bothersome refractory fecal incontinence; and those with combined urinary and bowel symptoms. Limited evidence supports SNM for the following patients: those with interstitial cystitis (IC)/bladder pain syndrome (BPS), though it may be an option for these patients after appropriate assessment; and those with neurogenic lower urinary tract dysfunction (NLUTD). There is minimal evidence supporting the use of SNM in patients with non-IC/BPS pelvic pain, and the society does not recommend SNM for these patients. Notably, this best practice statement also includes recommendations for SNM in pediatric patients. The society recommends SNM in children who have failed an extended course of behavioral modification, biofeedback, and pharmacotherapy. The society also cautions that safety and effectiveness have not been established in pediatric patients and that implantation in these patients may be more challenging.¹⁵

In their standardization document on the treatment of daytime urinary incontinence, the 2017 International Children's Continence Society (ICCS) notes that studies have demonstrated the efficacy of SNM in improving neurogenic bladder dysfunction, with specific benefits reported in pediatric OAB, dysfunctional elimination syndrome, and Fowler syndrome. The society also recommends that SNM be adjunctive to standard urotherapy and pharmacotherapy, or as an alternative to these treatments in children unable to tolerate them.³⁸

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Policy Revision History/Information

Original Date: February 06, 2025		
Review History		
Version 1.1	11/18/2025	Policy re-formatted to reflect current template. Policy updated to reflect CMS updates: Link and reference for L34328 updated 10/23/2025 with no coverage changes by CMS. L37360 removed from policy – Retired by CMS 10/23/2025. Updated CMS-related references.
Version 2	01/29/2026	Annual review. CPT codes 64561 and 64581 added and criteria modified to accommodate sacral nerve stimulation trial. Minor edits to medical necessity criteria for clarity and usability. Organized and expanded the Harms and Benefits and Medical Evidence sections (reference numbers 9, 11-15, 18, 21-25, 27-31, 34-38).
Version 2.1	02/12/2026	Revision. CPT codes 64555, 64575, 64596, 64999 added (no criteria changes required).

Version 2.2	04/21/2026	Added HCPCS codes L8680, L8688, L8681, C1767, C1778, C1787, and C1894 (no criteria changes required). Updated CMS links and references for A53359 and A55835.



Cohere Medicare Advantage Policy – Gastric Pacing/Electrical Stimulation

Clinical Policy for Medical Necessity Review

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Important Notices

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Policy Information:

Specialty Area: Musculoskeletal Care / Gastroenterology / Urology

Policy Name: Cohere Medicare Advantage Policy - Gastric Pacing/Electrical Stimulation

Policy Number: CHP-021-2.1

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Gastric Pacing/Electrical Stimulation

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁸

- [National Coverage Determination \(NCD\). Electrical nerve stimulators \(160.7\)](#)
- [National Coverage Determination \(NCD\). Sacral nerve stimulation for urinary incontinence \(230.18\)](#)
 - [Billing and Coding: Sacral nerve stimulation for urinary and fecal incontinence \(A53359\)](#)
 - [Billing and Coding: Sacral nerve stimulation for urinary and fecal incontinence \(A55835\)](#)
- [Local Coverage Determination \(LCD\). Peripheral nerve stimulation \(L34328\)](#)
 - [Billing and Coding: Peripheral Nerve Stimulation \(A55530\)](#)
- [Local Coverage Determination \(LCD\). Sacral nerve stimulation for the treatment of urinary and fecal incontinence \(L39543\)](#)
 - [Billing and Coding: Sacral nerve stimulation for the treatment of urinary and fecal incontinence \(A59332\)](#)

Description

Electrical stimulation is a treatment modality in which inappropriate or excessive neural activity is modulated using electrical impulses. These impulses are delivered by a surgically implanted device and target specific nerves. Gastric electrical stimulation (GES) involves the delivery of electrical pulses to the stomach wall in order to modulate the enteric nervous system and decrease symptoms of impaired gastric neural regulation. Electrical stimulation is delivered via two leads implanted in the smooth muscle of the stomach and connected to a subcutaneously implanted pulse generator.⁹⁻¹¹

Peripheral nerve stimulation (PNS) is a United States Food & Drug Administration-authorized treatment for acute and chronic pain affecting the lower back, extremities, trunk, head, and face. A neurostimulator device is implanted, and electrodes are placed near the specific affected peripheral nerves.^{5,12-14} In sacral neurostimulation/neuromodulation (SNM), a neurostimulator device is positioned to deliver nonpainful electrical impulses to the sacral nerves, which control bowel, bladder, and pelvic floor function.^{7,9,10,15-17}

Medical Necessity Criteria

Indications

Electrical neurostimulation is considered appropriate if **ANY** of the following is **TRUE**:

- **Gastric electrical stimulation (GES)** is considered appropriate if **ALL** of the following are **TRUE**:
 - Documented confirmation of gastroparesis (gastric emptying delay with greater than 10% tracer retention at 4 hours) on a 4-hour scintigraphic or breath test gastric emptying study^{9,16,18}; **AND**
 - Nausea or vomiting as the predominant symptom^{9,16}; **AND**
 - Other anatomic/organic causes have been excluded with upper endoscopy and selective imaging, if indicated^{9,16}; **AND**
 - Failure of or intolerance to **ALL** of the following conservative measures:
 - Dietary modification (e.g., small particle diet)^{9,16}; **AND**
 - Over-the-counter (OTC) therapy^{9,16}; **AND**
 - Anti-emetics^{9,16}; **AND**
 - Prokinetics (e.g., erythromycin, domperidone, metoclopramide, and prucalopride)^{9,16}; **AND**
 - Conservative measures trialed for a duration of 1 year or more; **OR**
- **Peripheral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**^{5,12,14}:
 - Appropriate proper patient education, discussion, and disclosure of risks and benefits⁵; **AND**
 - Appropriate surgical candidate (i.e., no infection or relevant medical risks)⁵; **AND**
 - Chronic, severe pain for at least 3 months; **AND**
 - Failure of less invasive treatment modalities and medications^{5,12}; **AND**
 - Formal psychological screening by a mental health professional⁵; **AND**
 - No active substance abuse⁵; **AND**
 - Successful stimulation trial as defined by greater than or equal to 50% reduction in pain intensity; **OR**

- **Sacral nerve stimulation** is considered appropriate if **ALL** of the following are **TRUE**^{2,7}:
 - **ANY** of the following symptoms:
 - Chronic fecal incontinence with greater than two incontinent episodes on average per week for a duration of more than 6 months^{2,7}; **OR**
 - Nonobstructive urinary retention^{2,7}; **OR**
 - Urinary urge incontinence^{2,7}; **OR**
 - Urinary frequency syndrome^{2,7}; **AND**
 - Ability to record voiding diary data such that clinical results of the implant procedure may be properly evaluated^{2,7}; **AND**
 - Appropriate surgical candidate (no infection or relevant medical risks)^{2,7}; **AND**
 - Failure or intolerance of conventional therapy (behavioral, pharmacologic, dietary, or surgical corrective therapy)^{2,7}; **AND**
 - **ANY** of the following sacral nerve stimulation procedures:
 - Screening trial; **OR**
 - Permanent implantation after a successful stimulation trial as defined by **ALL** of the following:
 - Greater than or equal to 50% sustained reduction in symptoms^{2,7}; **AND**
 - For greater than 48 hours; **OR**
- **Removal, revision, or replacement** of an existing neurostimulation device that is nonfunctioning, has a depleted battery, or is damaged (fractured leads or other damage).¹⁻⁸

Non-Indications

Electrical neurostimulation is not considered appropriate if **ANY** of the following is **TRUE**:

- **Gastric pacing/gastric neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{9,16}:
 - Current opioid use; **OR**
 - Cannabinoid hyperemesis; **OR**
 - Predominant symptom of gastroparesis is abdominal pain, bloating, or discomfort; **OR**
 - As treatment for **ANY** of the following in the absence of other criteria:
 - Congenital hypertrophic pyloric stenosis; **OR**
 - Cyclic vomiting syndrome; **OR**
 - Diabetes mellitus; **OR**
 - Eating disorder; **OR**
 - Functional dyspepsia; **OR**
 - Obesity; **OR**
 - Psychogenic vomiting; **OR**
- **Peripheral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{5,14}:
 - Angina pectoris; **OR**
 - Diffuse polyneuropathy; **OR**
 - Fibromyalgia; **OR**
 - Nociceptive pain in trunk or lower back; **OR**
 - Phantom limb pain; **OR**
- **Sacral neurostimulation** is not considered appropriate if **ANY** of the following is **TRUE**^{2,7}:
 - Benign prostatic hypertrophy; **OR**
 - Chronic constipation; **OR**
 - Chronic pelvic pain in the absence of other criteria; **OR**
 - Diabetes with peripheral nerve involvement; **OR**
 - Fecal incontinence related to **ANY** of the following¹⁸⁻²⁰:
 - Rectal intussusception; **OR**
 - Anorectal malformation; **OR**
 - Peripheral neuropathy or complete spinal cord injury; **OR**
 - Multiple sclerosis; **OR**
 - Stress incontinence; **OR**
 - Urethral obstruction or stricture.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial

	electrode array
64999	Unlisted procedure, nervous system

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for electrical neurostimulation may include:

- Adverse effects from delayed or denied treatment, such as continued and worsening nausea, vomiting, pain, or incontinence.^{[21-23](#)} These symptoms may lead to reductions in quality of life and downstream effects, including impaired nutritional status, increased need for nutritional supplementation, and increased use of healthcare services.^{[21](#)}
- Device-associated risks are possible with the implantation of nerve stimulators. These complications include infection, pain at the stimulation site, erosion of the device through the skin or stomach wall, excessive bleeding, and inadequate treatment of symptoms.^{[11,15,21-24](#)}
- Risks with inappropriate surgical procedures include infection, bleeding, injury to neurovascular structures, lead migration, anesthetic risk, and the need for repeat or additional procedures.^{[11,15,21-24](#)}
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for electrical neurostimulation may include:

- Improved patient selection for electrical neurostimulation, resulting in better long-term outcomes. Ideal candidates for gastric stimulation should have a predominance of nausea/vomiting symptoms and be free from narcotic use prior to electrode implantation.^{[21](#)}
- Maintenance of rigorous patient safety standards aligned to best available evidence. Patients with active opioid use treated with gastric stimulation

may experience poor, inconsistent, or short-lived relief from their gastric symptoms, which may be driven or exacerbated by the opioid use.²⁵ This may lead to downstream increases in opioid use and further worsening of symptoms.

- Nerve stimulators may offer symptom relief for patients who have exhausted other treatment options, including patients with intractable vomiting or recurrent incontinence. Non-opioid treatment of chronic pain may be possible with peripheral nerve stimulators.
- Compared to traditional treatments, including major surgical procedures such as urostomy/colostomy formation for chronic incontinence, nerve stimulators are less invasive and less expensive. Minimally invasive procedures generally offer a better patient safety profile, a shorter recovery period, and a minimal (or sometimes eliminated) hospital stay.
- Enhanced overall patient satisfaction and healthcare experience.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Gastric electrical stimulation (GES)

A 2024 systematic review and meta-analysis by Saleem et al. included 730 patients with gastric stimulators. One year after implantation, patients experienced a significantly improved gastrointestinal total symptom score (TSS), reduced vomiting frequency, improved gastric emptying study results, and enhanced quality of life. The authors concluded that gastric electrical stimulation remains a viable treatment option for gastroparesis refractory to traditional therapies, acknowledging that gastroparesis is a high-burden disease with a high mortality rate.²⁶

Cassidy et al. (2024) reported long-term follow-up in 157 patients who underwent GES for medically refractory gastroparesis. The authors reported decreased severity of all nine gastroparesis symptoms evaluated at both 1-year and 5-year timepoints. Additionally, decreases were observed in prokinetic and antiemetic medication use and in gastroparesis-related hospitalizations, and patient satisfaction was high. Only five patients required explant of the device, one due to a pocket infection and four due to insufficient symptom relief. Overall, the authors concluded that GES can provide enduring symptom relief, medication-use reduction, and hospitalization decreases.¹¹

Orsagh-Yentis et al. (2021) reported outcomes of GES in 85 pediatric patients (mean age, 15.8 years; range, 2-19 years). The authors reported post-implantation decreases in all individual symptoms measured, including vomiting frequency, vomiting severity, early satiety, bloating, postprandial fullness, and epigastric pain. Notably, feeding tube use decreased from 72.7% at baseline to 29.9% at final follow-up, and total parenteral nutrition (TPN) dependence decreased by more than half. Overall quality of life and health measures improved, and patient and family satisfaction with the procedure was high.²⁷

Islam et al. (2016) reported outcomes in 97 children (mean age, 13.7 years; range, 2-19 years) with refractory gastroparesis who underwent GES. Patients

had delayed gastric emptying on scintigraphy, a long duration of symptoms (mean 3.5 years), previous and ongoing use of promotility, antiemetic, pain, and/or antireflux agents. A majority (66%) of patients reported at least one previous procedure, including fundoplication. Symptom improvement was reported in 66 patients, with improved symptom scores at 1, 6, and 12 months after implantation. Symptom recurrence and device removal were reported in seven patients. The authors concluded that GES is safe and effective in pediatric patients with intractable gastroparesis.²⁸

The American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) have published guidance on the use of electrical stimulation for gastroparesis. The 2025 AGA clinical practice guideline on management of gastroparesis contains 12 recommendations on diagnosis and treatment, including coverage of medical, surgical, and other therapies. Regarding gastroparesis refractory to medical therapy, the AGA recommends against routine use of GES. The comment associated with this conditional recommendation states that patients and providers who value potential improvement and symptom relief over the potential for adverse events may reasonably elect GES. The guidelines further note that GES should be used only in select patients with medically refractory gastroparesis and that patients should be informed that, while GES can improve nausea and vomiting, it is not expected to alleviate abdominal pain.¹⁸ Similarly, the AGA's 2022 clinical practice guidelines encourage clinicians to consider electrical stimulation only for patients with intractable and refractory nausea and vomiting, provided that they had no success with conventional therapy and were not taking opioids. These professional guidelines underscore the importance of appropriate patient selection.²⁹

Peripheral nerve stimulation (PNS)

Manchikanti et al. (2025) conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) examining the effectiveness of PNS for chronic pain management. Their final analysis included nine studies. At 1-month follow-up, significantly fewer patients treated with PNS reported pain and functional disability compared to control group patients. These effects were maintained at both the 3-month and 12-month follow-ups, indicating that PNS may have a meaningful long-term impact on pain and daily functioning. The authors concluded that the overall evidence supporting PNS

for pain treatment was level III (fair), with moderate certainty and moderate strength of evidence. The authors further outlined seven criteria to guide patient selection for PNS. These criteria included: documented function-limiting moderate to severe pain (average pain score greater than or equal to 5) that has persisted for at least 3 months; documented failure of less invasive treatment for at least 4 weeks; absence of surgical contraindications; completion of patient education; no substance abuse; psychological evaluation; and successful trial stimulation.¹⁴

D'Souza et al. (2025) reported a broader systematic review and meta-analysis of studies examining the use of PNS for chronic pain. Their final analysis included both RCTs and observational studies, comprising 106 studies and 9272 patients. The authors reported that PNS decreased pain intensity at all time points evaluated: 3, 6, 12, and 24 months. The authors concluded that implantable PNS provides enduring and clinically meaningful relief of chronic pain that is refractory to conventional therapies. The authors also noted that these effects did not differ by study type, suggesting that the pain-reducing effects of PNS are not limited to patients meeting narrow clinical trial selection criteria.³⁰

Peer-reviewed studies on the use of PNS in pediatric patients are limited. A 2024 case series reported the use of ultrasound-guided suprascapular nerve PNS in the treatment of cancer-related pain in two pediatric patients (ages 16 years and 17 years). Both patients had trialed medical pain relief and either did not tolerate or were unable to attempt other pain relief strategies. The average pain score of one patient decreased from 10 at baseline to 7 in the first week following PNS, and then to 4 at 60-day follow-up. The other patient's average pain score decreased from 8 at baseline to 5 at 30-day follow-up, further decreasing to 3 at 60-day follow-up. The authors concluded that PNS can be safe and effective in decreasing cancer-related pain in pediatric patients.³¹

Similarly, Garya et al. (2023) reported that PNS successfully decreased pediatric neuropathic leg pain in a 15-year-old patient. Two years after an accident, the patient reported significant thigh and knee pain despite conservative treatments including physical therapy, mobility exercises, use of a sleeve/brace, and pain medication. Two months following implantation of

the stimulator, the patient reported significant pain relief and improved quality of life. The authors concluded that PNS holds promise as a treatment option for pediatric neuropathic pain, cautioning that it may not be appropriate for all pediatric patients. Specifically, the authors noted that PNS may be more suitable for adolescent patients than for younger pediatric patients. Additionally, the authors noted that cognitive delays that prevent a patient from expressing adverse effects may disqualify a patient from PNS, and that young children (under 10 years of age) may be unable to handle and care for the device.²⁴

The 2025 American Society of Pain and Neuroscience (ASPN) consensus guideline for the use of PNS in the treatment of chronic pain and neurological diseases reviews the peer-reviewed research on PNS and presents 18 consensus statements on its efficacy and optimal use. Consensus guideline statements include: anesthetic nerve blocks, while potentially useful in determining patient anatomy and identifying stimulation target nerves, should not be considered prognostic in predicting a response to PNS; stimulation platform (external, implantable, or hybrid) should be determined through shared decision making between the patient and the provider; consideration of future magnetic resonance imaging (MRI) should inform platform selection; and high level evidence supports the use of PNS in patients with chronic pain.¹²

The 2025 ASPN consensus guideline on the use of 60-day PNS cites research demonstrating that traditional 10-14 day stimulation trial periods may not be adequate for a significant proportion of patients. These relatively short trial periods may both falsely identify patients with early yet transient responses to stimulation as good candidates for PNS and those with delayed yet enduring responses as bad candidates. The guidelines contain strong recommendations for a 60-day PNS in the treatment of the following pain etiologies: chronic low back pain (LBP) with central contributions, postoperative refractory knee pain, phantom and residual limb pain, and postamputation pain. Moderate recommendations are issued for: chronic LBP, chronic LBP after facet radiofrequency ablation, post-operative refractory foot and ankle pain, neuropathic pain, occipital neuralgia, inoperable shoulder pain, and post-operative refractory shoulder pain.¹³

The 2024 American Society of Interventional Pain Physicians (ASIPP) evidence-based clinical guidelines on the use of implanted peripheral nerve stimulators to manage chronic pain include a review of PNS research and recommendations for its use. Based on fair-quality evidence, a moderate-strength recommendation supports the use of peripheral stimulators in a patient with moderate or severe chronic pain that has failed two or more conventional treatments and has successfully responded to a trial period with a test stimulation device. The authors note that the evidence base remains low-quality and heterogeneous, suggesting that this has hindered the field's ability to reach a definitive consensus regarding appropriate use. The 2022 American Society of Pain and Neuroscience (ASPN) guidelines similarly review specific scenarios for peripheral nerve stimulation. All discussed scenarios have a recommendation of level B or C ("recommendable" or "neither recommendable nor inadvisable").^{[32,33](#)}

Sacral nerve stimulation

Amundson et al. (2025) conducted a systematic review and meta-analysis comparing the efficacy of sacral nerve stimulation/sacral neuromodulation (SNM) and implantable tibial neuromodulation (iTNM) in the management of overactive bladder (OAB). Their final analysis included 20 studies, with 1416 patients treated with SNM and 350 treated with iTNM. They reported no differences in treatment efficacy between SNM and iTNM, with similar reductions in urgency, OAB, and incontinence episodes, and similar improvements in quality of life. Additionally, both devices had similarly low complication rates. The authors concluded that neuromodulation, whether via SNM or iTNM, is safe and effective for managing urinary complications.^{[34](#)}

Faure et al. (2025) reported that SNM was successful in treating idiopathic overactive bladder (OAB) in four pediatric patients (mean age 8.5 years) and non-neurogenic urinary retention in three patients (mean age 16 years). All patients had unsuccessfully attempted conservative treatments, including urotherapy and anticholinergics, prior to SNM. Complications were minimal and included wound infection and device dysfunction, leading to surgical revision in two patients. The authors concluded that SNM is safe and effective in pediatric patients with refractory non-neurogenic vesico-sphincter disorders.^{[35](#)}

Besendörfer et al. (2024) reported a prospective trial investigating the efficacy of SNM in 15 pediatric patients (mean age, 8 years; range, 4-17 years) with refractory neuronal enteropathies. The authors reported improved defecation frequency in eight patients and improved fecal incontinence in nine patients. Notably, eight of the patients had Hirschsprung's disease, which results in severe gastrointestinal motility dysfunction, with SNM successfully improving symptoms in seven of these. Findings were stable at 12-month follow-up. The authors concluded that SNM is a promising treatment for chronic constipation and fecal incontinence in pediatric patients.³⁶

The 2024 American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guideline on the diagnosis and treatment of OAB comprises 33 statements that cover various treatment options, ranging from pharmacotherapy to indwelling catheters. The guidelines strongly recommend noninvasive treatments, including bladder training, fluid management, pelvic floor muscle therapy, transvaginal electrical stimulation, and pharmacotherapy prior to consideration of minimally invasive procedures. Minimally invasive procedures may include sacral neuromodulation, tibial nerve stimulation, and intradetrusor botulinum toxin injection. The guidelines note that these treatments have high success rates, durability, and patient satisfaction. Specifically, these treatments can decrease voiding frequency, nocturia, and the number of urgency and incontinence episodes.³⁷

The 2023 American Society of Colon and Rectal Surgeons (ASCRS) practice guideline on the treatment of fecal incontinence provides SNM with a conditional recommendation due to the limited research on sacral nerve stimulation. The literature review notes that sacral nerve stimulation can result in at least a 50% improvement in symptoms for many patients. Moreover, for some patients, SNM may be more effective than optimal medical therapy. The American Urological Association (AUA) guideline on adult neurogenic lower urinary tract dysfunction contains guidance for the use of electrical stimulation. A variety of common urological problems, including overactive bladder and urge incontinence, improve with sacral nerve stimulation when patients have failed traditional therapy. An exception to this is urinary retention, which does not require failure of conservative

therapy if sacral nerve stimulation is considered as an alternative to intermittent self-catheterization.^{10,17}

The 2017 International Continence Society (ICS) best practice statement on the use of sacral neuromodulation (SNM) states that SNM should not be considered a first-line therapy for either bowel or bladder disorders, and recommends initial trials of conservative measures, including physical and behavioral therapies. The statement goes on to recommend that SNM be offered to several groups of patients including: those with treatment-resistant OAB regardless of the presence of incontinence; those with Fowler's syndrome, voiding dysfunction, and non-obstructive urinary retention; those with bothersome refractory fecal incontinence; and those with combined urinary and bowel symptoms. Limited evidence supports SNM for the following patients: those with interstitial cystitis (IC)/bladder pain syndrome (BPS), though it may be an option for these patients after appropriate assessment; and those with neurogenic lower urinary tract dysfunction (NLUTD). There is minimal evidence supporting the use of SNM in patients with non-IC/BPS pelvic pain, and the society does not recommend SNM for these patients. Notably, this best practice statement also includes recommendations for SNM in pediatric patients. The society recommends SNM in children who have failed an extended course of behavioral modification, biofeedback, and pharmacotherapy. The society also cautions that safety and effectiveness have not been established in pediatric patients and that implantation in these patients may be more challenging.¹⁵

In their standardization document on the treatment of daytime urinary incontinence, the 2017 International Children's Continence Society (ICCS) notes that studies have demonstrated the efficacy of SNM in improving neurogenic bladder dysfunction, with specific benefits reported in pediatric OAB, dysfunctional elimination syndrome, and Fowler syndrome. The society also recommends that SNM be adjunctive to standard urotherapy and pharmacotherapy, or as an alternative to these treatments in children unable to tolerate them.³⁸

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Policy Revision History/Information

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Version 1.1	11/18/2025	Policy re-formatted to reflect current template. Policy updated to reflect CMS updates: Link and reference for L34328 updated 10/23/2025 with no coverage changes by CMS. L37360 removed from policy – Retired by CMS 10/23/2025. Updated CMS-related references.
Version 2	01/29/2026	Annual review. CPT codes 64561 and 64581 added and criteria modified to accommodate sacral nerve stimulation trial. Minor edits to medical necessity criteria for clarity and usability. Organized and expanded the Harms and Benefits and Medical Evidence sections (reference numbers 9, 11-15, 18, 21-25, 27-31, 34-38).
Version 2.1	02/12/2026	Revision. CPT codes 64555, 64575, 64596, 64999 added (no criteria changes required).



Cohere Medicare Advantage Policy – Laparoscopic Hiatal Hernia Repair and Anti-GERD Surgical Treatments

Clinical Policy for Medical Necessity Review

Version: 3

Cohere Health UMC Approval Date: December 11, 2025

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Important Notices

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Policy Information:

Specialty Area: Gastroenterology

Policy Name: Cohere Medicare Advantage Policy - Laparoscopic Hiatal Hernia Repair and Anti-GERD Surgical Treatments

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Laparoscopic Hiatal Hernia Repair and Anti-GERD Surgical Treatments

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁴

- [Local Coverage Determination \(LCD\). Endoscopic treatment of GERD \(L34659\)](#)
 - [Billing and Coding. Endoscopic treatment of GERD \(A56395\)](#)
- [Local Coverage Determination \(LCD\). Select minimally invasive GERD procedures \(L35080\)](#)
 - [Billing and Coding. Select minimally invasive GERD procedures \(A56863\)](#)

Description

A single laparoscopic hiatal hernia repair is sufficient for most patients. Laparoscopic repair with suturing of the hiatal pillars followed by fundoplication is the standard medical practice for hiatal hernia . Mesh reinforcement, commonly located at the posterior esophageal hiatus, is commonly used to lower recurrence rates.⁵ Additionally, fundoplication is used to repair paraesophageal hiatal hernia . Laparoscopic esophagogastric fundoplasty is a procedure that involves wrapping the upper part of the stomach around the lower part of the esophagus.⁶

Medical Necessity Criteria

Indications

Laparoscopic anti-reflux surgery, laparoscopic hiatal hernia repair, or transoral incisionless fundoplication (TIF) procedure is considered appropriate if **ALL** of the following are **TRUE**:

- **ALL** of the following objective criteria are met⁷:
 - High-resolution manometry or barium esophagram rules out achalasia;
AND
 - **ANY** of the following that confirms gastroesophageal reflux disease (GERD) (i.e., abnormal esophageal acid exposure):
 - Upper endoscopy (e.g., in the form of reflux esophagitis, peptic stricture, or Barrett's esophagus); **OR**
 - Ambulatory esophageal pH-metry; **OR**
 - Ambulatory esophageal pH-impedance testing; **AND**
- **ANY** of the following:
 - Anti-reflux surgery (fundoplication with or without hiatal hernia repair) is considered appropriate with **ANY** of the following:
 - Without hiatal hernia repair (fundoplication only) and **ANY** of the following:
 - Gastroesophageal reflux symptoms or GERD complications (e.g., reflux esophagitis) not fully responsive to medical treatment^{A 8,9}; **OR**
 - Gastroesophageal reflux symptoms present when medical treatment is contraindicated (e.g., intolerant or allergic to proton pump inhibitors (PPIs) and/or histamine receptor antagonists); **OR**
 - The patient has **ANY** of the following¹⁰:
 - Documented evidence of micro-aspiration; **OR**
 - High-risk for complications of micro-aspiration (e.g., lung transplant recipient); **OR**
 - With hiatal hernia (fundoplication with hiatal hernia repair) and **ANY** of the following:
 - Gastroesophageal reflux symptoms or GERD complications (e.g., reflux esophagitis) not fully responsive to medical treatment^{A 8,9}; **OR**

- Gastroesophageal reflux symptoms present when medical treatment is contraindicated (e.g., intolerant or allergic to PPIs and/or histamine receptor antagonists); **OR**
- The patient has any hiatal hernia with **ANY** of the following¹⁰:
 - Documented evidence of micro-aspiration; **OR**
 - High-risk for complications of micro-aspiration (e.g., lung transplant recipient); **OR**
- Pediatric patient with **ALL** of the following^{11,12}:
 - **ANY** of the following:
 - Symptoms refractory to optimal therapy (e.g., medication and lifestyle changes), after appropriate evaluation to exclude other underlying diseases¹³; **OR**
 - Life-threatening complications (e.g. cardiorespiratory failure) of GERD after failure of optimal medical treatment¹³; **OR**
 - Chronic condition (e.g., neurologically impaired, cystic fibrosis) with a significant risk of GERD-related complications that significantly impact the patient's quality of life¹⁴; **OR**
 - As an alternative to lifelong pharmacotherapy for control of signs and/or symptoms of GERD; **AND**
 - **ANY** of the following procedures:
 - Fundoplication without hiatal hernia repair with **ANY** of the following:
 - Gastroesophageal reflux symptoms or GERD complications (e.g., reflux esophagitis) not fully responsive to medical treatment (e.g., unsuccessful treatment with proton pump inhibitors [PPIs] or histamine receptor antagonists for at least 3 successive months under the direction of a healthcare professional)^{8,9}; **OR**
 - Gastroesophageal reflux symptoms present when medical treatment is contraindicated (e.g., intolerant or allergic to PPIs and/or histamine receptor antagonists); **OR**
 - The patient has **ANY** of the following¹⁰:
 - Documented evidence of micro-aspiration; **OR**
 - High-risk for complications of micro-aspiration (e.g., lung transplant recipient); **OR**
 - Fundoplication with hiatal hernia repair and with **ANY** of the following:

- Gastroesophageal reflux symptoms or GERD complications (e.g., reflux esophagitis) not fully responsive to medical treatment (e.g., unsuccessful treatment with PPIs or histamine receptor antagonists for at least 3 successive months under the direction of a healthcare professional)^{8,9}; **OR**
- Gastroesophageal reflux symptoms present when medical treatment is contraindicated (e.g., intolerant or allergic to PPIs and/or histamine receptor antagonists); **OR**
- The patient has any hiatal hernia with **ANY** of the following¹⁰:
 - Documented evidence of micro-aspiration; **OR**
 - High-risk for complications of micro-aspiration (e.g., lung transplant recipient); **OR**
- Laparoscopic hiatal hernia repair with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement is considered appropriate if **ALL** of the following^{15,16}:
 - Hiatal hernia is confirmed by **ANY** of the following¹⁷:
 - Cross-sectional imaging (CT or MRI); **OR**
 - Contrast radiography (barium esophagram or upper GI series); **OR**
 - Esophagogastroduodenoscopy (EGD); **OR**
 - Esophageal manometry; **OR**
 - Detection during preoperative workup for bariatric surgery; **AND**
 - Hiatal hernia is designated as type 2, 3, or 4 and is associated with **ANY** of the following symptoms:
 - Acute rotation of the stomach (gastric volvulus), including but not limited to upside-down stomach (UDS)⁶; **OR**
 - Gastric outlet obstruction caused by the hernia⁶; **OR**
 - Suspected or documented gastric strangulation¹⁸; **OR**
 - Dysphagia or post-prandial fullness resulting from hernia-related mass effect and extrinsic compression on the lower esophagus¹⁹; **OR**
 - Persistent anemia in the presence of a Cameron lesion when other causes have been excluded²⁰; **OR**
- Revision of prior hiatal hernia repair or fundoplication is considered appropriate with **ALL** of the following^{5,16,21-23}:
 - Evidence of failure of prior operation, including but not limited to recurrent hernia or migration of fundoplasty; **AND**

- Recurrent symptoms (e.g., any of the symptoms described above for initial procedure) or recurrent GERD symptoms that are refractory despite adequate trial of medical therapy with PPI, PCABs, and/or histamine antagonist; **OR**
- TIF (including the EsophyX™ device) is considered appropriate with **ALL** of the following³:
 - Symptomatic chronic GERD (at least 6 months of symptoms)¹; **AND**
 - Symptoms must not be completely responsive to PPIs, as indicated by **ANY** of the following¹:
 - **ALL** of the following:
 - GERD health-related quality of life (HRQL) scores of less than or equal to 12 while on PPIs; **AND**
 - GERD HRQL scores of greater than or equal to 20 when off PPIs for 14 days; **OR**
 - A difference of greater than or equal to 10 points in GERD HRQL scores between off and on therapy; **AND**
 - **ANY** of the following:
 - No hiatal hernia; **OR**
 - Hiatal hernia less than or equal to 2 cm, including instances where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure before the TIF procedure.¹

Non-Indications

Laparoscopic anti-reflux surgery, laparoscopic hiatal hernia repair, or transoral incisionless fundoplication (TIF) procedure is not considered appropriate if **ANY** of the following is **TRUE**:

- Laparoscopic hiatal hernia repair with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement with **ANY** of the following¹⁰:
 - The patient has an asymptomatic hiatal hernia and no objective evidence of GERD or GERD complications; **OR**
 - The patient does not meet the criteria as outlined above; **OR**
 - The request is for open surgery for hiatal hernia repair; **OR**
- Magnetic sphincter augmentation (LINX® Reflux Management System), as the procedure is clinically unproven and not medically necessary due to inconclusive evidence of its effectiveness^{3,14}; **OR**
- Endoluminal treatment for GERD using the Stretta® procedure, the Bard EndoCinch™ Suturing System, Plicator™, Enteryx®, or similar treatments, as these procedures are not considered reasonable and necessary for the diagnosis or treatment of an injury or disease^{1,3}; **OR**
- TIF with **ANY** of the following:
 - The patient has recurrent symptoms or other evidence of failure following a prior TIF^{1,3}; **OR**
 - The patient is less than or equal to 17 years of age^{14,24}; **OR**
 - Repeat TIF is clinically unproven based on inconclusive evidence of its effectiveness and is not medically necessary; **OR**
 - The patient has a hiatal hernia greater than 2 cm, except where the hernia has been reduced to 2 cm or less by a successful laparoscopic hernia reduction procedure before the TIF procedure³; **OR**
 - BMI greater than 35³; **OR**
 - Esophagitis LA grade higher than B³; **OR**
 - Barrett's esophagus greater than 2 cm³; **OR**
 - Presence of achalasia³; **OR**
 - Presence of esophageal ulcer³; **OR**
 - No appropriate trial of PPIs.³

Definitions

^AMedical treatment for gastroesophageal reflux disease (GERD) symptoms or complications: unsuccessful treatment with proton pump inhibitors (PPIs), histamine receptor antagonists, or a potassium-competitive acid blocker (PCAB) for at least 3 successive months under the direction of a healthcare professional^{8,9}

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43280	Laparoscopy, surgical, esophagogastric fundoplasty (e.g., Nissen, Toupet procedures)
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh
43283	Laparoscopy, surgical, esophageal lengthening procedure (e.g., Collis gastroplasty or wedge gastroplasty) (List separately in addition to code for primary procedure)
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for laparoscopic hiatal hernia repair and anti-GERD surgical treatments may include:

- The surgical placement of mesh to prevent the recurrence of hiatal hernias has been associated with infection, erosion, seroma, and pain. The use of synthetic mesh has been associated with the development of esophageal erosion, stricture, dysphagia, obstruction, and esophageal stenosis.¹⁷ Less common adverse effects of anchoring a mesh to the diaphragm include cardiac injuries, which can manifest as cardiac tamponade, especially when a helical tacker is used in this region.
- Robotic surgery in laparoscopic hiatal hernia repair and anti-GERD surgery using the DaVinci system is subject to substantial costs and can result in higher rates of esophageal perforation and respiratory failure compared to conventional laparoscopy. Moreover, improvements in operating time, intraoperative and postoperative complications, and the length of hospital stay between robotic-assisted surgery and conventional laparoscopic hiatal hernia repair are debatable.^{17,25}
- Depending on the surgical technique, symptoms (including the hiatal hernia itself) may recur and necessitate further medical or invasive management.^{26,27}
- The rate of repeat fundoplication was 12% in a retrospective review of 823 pediatric patients.¹¹ Raza et al. (2025) noted that additional research in the pediatric population is needed on surgical interventions and long-term impact of future complications.¹⁴

- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for laparoscopic hiatal hernia repair and anti-GERD surgical treatments may include:

- Improved patient selection may result in better long-term outcomes, including a long-term cure for persistent heartburn, acid reflux, chest pain, dysphagia, and other debilitating upper gastrointestinal signs and symptoms. Additional expected outcomes include long-term acid suppression (which reduces the risk of progression to esophageal adenocarcinoma)^{10,28} and decreased hernia recurrence after laparoscopic paraesophageal hernia repair and mesh reinforcement (results are similar with synthetic and biologic meshes).¹⁷
- Adequate symptom control leads to freedom from long-term proton pump inhibitor (PPI) use, which confers potential risks to bone and kidney health, as well as an increased risk of pneumonia.²⁹
- For pediatric patients, overall success rates of anti-reflux surgery and the complete relief of GERD are good (median 86%).³⁰ Five-year survival rates increased from 59% to nearly 100% post-fundoplication.¹¹
- Enhanced overall patient satisfaction and healthcare experience.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Daly et al. (2024) conducted systematic reviews to evaluate (i) surgical treatment of asymptomatic hiatal hernia versus surveillance, (ii) the use of mesh versus not, (iii) performing a fundoplication versus no fundoplication; and (iv) Roux-en-Y gastric bypass (RYGB) versus repeat fundoplication for recurrent hiatal hernia, with the aim of providing guidance regarding surgical decision making in the treatment of hiatal hernia. The expert panel suggested that select asymptomatic patients may be offered surgical repair when objective evidence exists of reflux or micro-aspiration, or when patients are at high-risk for complications of micro-aspiration, even in the absence of objective findings, such as lung transplant patients. The panel also suggested that conversion to RYGB for the management of recurrent hiatal hernia may be appropriate in certain patients without obesity and with recurrent type II, III, or IV hiatal hernia. The evidence for the routine use of mesh in hiatal hernia repair was inconclusive, and the panel did not make a recommendation in this regard.¹⁰

Bhatt et al. (2023) systematically reviewed the perioperative outcomes of robotic and laparoscopic paraesophageal hernia (PEH) repair. Robotic surgery for large PEHs may offer benefits over standard laparoscopic approaches in decreasing conversion rates and duration of hospital stay. Some studies found a decrease in the need for esophageal lengthening procedures and fewer long-term recurrences. The perioperative complication rate is similar between the two techniques in most studies; however, one large study of nearly 170,000 patients in the early years of robotics adoption demonstrated a higher rate of esophageal perforation and respiratory failure in the robotic group (2.2% increase in absolute risk). Cost is another disadvantage of robotic repair when compared to laparoscopic repair. Limitations of this systematic review include the non-randomized and retrospective nature of the studies.²⁵

Geerts et al. (2023) reviewed the anatomic location of hiatal hernia recurrences to assess the high rates of recurrence despite mesh reinforcement. A retrospective analysis of video clips from the procedure in 54 patients who underwent revision hiatal hernia surgery revealed that the

left-anterior quadrant of the esophageal hiatus was involved in 43 patients (80%), the right-anterior quadrant in 21 patients (39%), the left-posterior quadrant in 21 patients (39%), and the right-posterior quadrant in 10 patients (19%). Based on these findings, the authors hypothesized that both posterior and anterior hiatal reinforcement might lower the recurrence rate of hiatal hernia.⁵

Analatos et al. (2020) report the results of a randomized, double-blind clinical trial (NCT04436159) that compares clinical outcomes and postoperative mechanical complications of para-oesophageal hernia repair employing total (Nissen) versus posterior partial (Toupet) fundoplication in 70 patients who had undergone hernia reduction and crural repair. Ogilvie dysphagia scores were stable at the 3- and 6-month follow-up in the Nissen group but significantly improved in the Toupet group at 6 months. At 6 months, Dakkak dysphagia scores were significantly higher in the Nissen group than in the Toupet group. Although quality of life (QoL) scores improved throughout the follow-up, at 3 and 6 months postoperatively, the absolute median improvement in the mental component of the QoL questionnaire was significantly higher in the Toupet group. At 6 months, radiologically confirmed recurrence of hernias occurred in 46% of patients in the Nissen group and 47% of patients in the Toupet group. Based on these findings, the authors conclude that Toupet fundoplication shows reduced obstructive complications and improved QoL compared with Nissen fundoplication following para-oesophageal hernia repair.²⁸

Several new therapies exist for the treatment of GERD and/or hiatal hernia. The LINX system seeks to control reflux with the implantation of a ring of magnetic beads around the distal esophagus, thereby creating an artificial sphincter. Broadly known as magnetic sphincter augmentation, this novel procedure appears to be well-tolerated by many patients, but the long-term efficacy and safety profile is not yet known simply by virtue of its short time on the market. Because this novel therapy does not yet have long-term efficacy results nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is premature to presume clinical outcomes and benefits, as well as long-term safety. For the same reason, this procedure cannot be considered equivalent or superior to the existing standard of surgical care.^{24,31,32}

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Policy Revision History/Information

Original Date: December 19, 2024		
Review History		
Version 2	03/06/2025	Created indications for fundoplication without hiatal hernia repair. Clarified hiatal hernia repair criteria to ensure non-approval of asymptomatic type 1 hiatal hernia (not medically appropriate). Provided non-indication for LINX, novel and not yet clinically proven or medically necessary. Per CMS guidance, provided indication for TIF approval, as well as coverage limitations as appropriate. Language taken directly from CMS and therefore not more stringent. Added references. Added indications for revision of prior hiatal hernia repair. Modified criteria to allow manometry of barium esophagram for r/o of achalasia.
Version 3	12/11/2025	Annual review. Simplified the Description. Per CMS guidance (L34659 and L35080), added non-indications for endoluminal treatment for GERD; added two non-indications under TIF.

		Added pediatric criteria under "anti-reflux surgery." Added items for pediatric patients to the Harms & Benefits section, including repeat fundoplication and overall success rates of anti-reflux surgery. Added CPT 43283.



Cohere Medicare Advantage Policy – Laparoscopic Hiatal Hernia Repair

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: December 19, 2024

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Guideline Information:

Specialty Area: Gastroenterology

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Laparoscopic Hiatal Hernia Repair

Benefit Category

Not applicable

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable national and local CMS Coverage.

- There are no NCDs or LCDs for laparoscopic hiatal hernia repair.

Recommended Clinical Approach

Hiatal hernia (HH) is a common structural defect of the diaphragm and occurs when the anterior stomach (fundus) protrudes through the opening where the esophagus passes from the thorax to the abdomen (diaphragmatic hiatus). HH may be asymptomatic or accompanied by gastroesophageal reflux disease (GERD) and is usually diagnosed through a barium swallow test or diagnostic imaging. HH are classified into 4 types. In type I (sliding hiatal hernia), the gastroesophageal junction (GEJ) moves headward through the hiatus into the thorax. In type II (paraesophageal hernia), the gastric fundus herniates through the hiatus into the thorax, but the GEJ remains in the abdomen. Type III is a combination of types I and II, where the GEJ and stomach herniate into the thorax. Type IV is a type III HH with herniation of other organs into the thorax, such as the colon and spleen.¹ The 3 dominant pathogenic theories for HH include: (1) intra-abdominal pressure forces the GEJ into the thorax; (2) esophageal shortening displaces the GEJ into the thorax; and (3) GEJ migrates into the chest due to a widening of the diaphragmatic hiatus due to molecular and cellular changes.²

Treatment for HH is directed at symptoms of GERD, if present. Symptomatic HH (types II–IV) may require repair using a transabdominal or transthoracic approach. Initial or revision laparoscopic HH repair may also be medically necessary during bariatric surgery. A single laparoscopic HH repair is sufficient for most patients. Laparoscopic repair with suturing of the hiatal pillars followed by fundoplication is the standard medical practice for HH. Mesh reinforcement, commonly located at the posterior esophageal hiatus, is commonly used to lower recurrence rates.³ Additionally, fundoplication is used to repair paraesophageal HH, reduce the risk of postoperative gastrointestinal reflux, and reinforce the repair to prevent a recurrence. Laparoscopic esophagogastric fundoplasty is a procedure that involves wrapping the upper part of the stomach around the lower part of the esophagus.¹ Physicians may choose this procedure for patients with gastroesophageal reflux. Laparoscopic HH surgery is generally not considered appropriate for patients with asymptomatic HH without objective evidence or a high risk of reflux or micro-aspiration.⁴

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of laparoscopic hiatal hernia repair. This process helps prevent incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- The surgical placement of mesh to prevent the recurrence of hiatal hernias has been associated with infection, erosion, seroma, and pain. The use of synthetic mesh has been associated with the development of esophageal erosion, stricture, dysphagia, obstruction, and esophageal stenosis.⁵ Less common adverse effects of anchoring a mesh to the diaphragm include cardiac injuries that manifest as cardiac tamponade, especially when a helical tacker is used in this region.¹⁵
- The risk associated with barium swallow radiography, commonly used to diagnose hiatal hernias, is exposure to radiation, which accumulates

over time and is closely linked to the total number of radiological examinations during one's lifetime.⁵

- Robotic surgery in laparoscopic hiatal hernia repair using the DaVinci system is subject to substantial costs and can result in higher rates of esophageal perforation and respiratory failure compared to conventional laparoscopy. Moreover, improvements in operating time, intraoperative and postoperative complications, and the length of hospital stay between robotic-assisted surgery and conventional laparoscopic hiatal hernia repair are debatable.^{5,13}
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Hiatal hernia surgery can provide a long-term cure for persistent heartburn, acid reflux, difficulty swallowing, and other upper gastrointestinal signs and symptoms.^{4,14}
- Hiatal hernia surgery can result in long-term acid suppression, which reduces the risk of progression to esophageal adenocarcinoma.^{4,14}
- Hernia recurrence decreases after laparoscopic paraesophageal hernia repair and mesh reinforcement, with similar results with synthetic and biologic meshes.⁵
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with minimizing potential harms, providing numerous clinical benefits, and helping avoid unnecessary complications from inappropriate care. In addition, using these criteria will create a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Laparoscopic hiatal hernia repair** with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement is considered appropriate if **ALL** of the following are **TRUE**¹⁻¹²:

◆ Hiatal hernia is confirmed by **ANY** of the following⁵:

- Diagnostic imaging; **OR**
- Radiology; **OR**
- Esophagogastroduodenoscopy (EGD); **OR**
- Manometry; **OR**
- Detection during preoperative workup for bariatric surgery^{8,16}; **AND**

◆ **ANY** of the following is **TRUE**:

- Acute rotation of the stomach (gastric volvulus), including but not limited to upside down stomach (UDS)¹; **OR**
- Gastric outlet obstruction caused by the hernia; **OR**
- Suspected or documented gastric strangulation; **OR**
- Dysphagia or post-prandial fullness resulting from hernia-related mass effect and extrinsic compression on the lower esophagus¹⁶; **OR**
- Gastroesophageal reflux symptoms or GERD complications (e.g. reflux esophagitis) incompletely responsive to medical treatment (e.g., unsuccessful treatment with proton pump inhibitors (PPIs), histamine receptor antagonists, or antacids, for at least 3 successive months under the direction of a healthcare professional)⁶; **OR**
- Gastroesophageal reflux symptoms present and medical treatment is contraindicated (e.g., intolerant or allergic to PPIs and/or histamine receptor antagonists); **OR**
- Persistent anemia when other causes have been excluded; **OR**
- The patient has an asymptomatic hiatal hernia and **ANY** of the following⁴:
 - Documented evidence of gastro-esophageal reflux (e.g., EGD evidence of reflux esophagitis or Barrett's esophagus, or abnormal parameters on ambulatory pH or impedance monitoring); **OR**

- Documented evidence of micro-aspiration; **OR**
- High risk for complications of micro-aspiration (e.g., lung transplant recipient); **OR**
- Detection during bariatric surgery.^{8,16}

Non-Indications

→ **Laparoscopic hiatal hernia repair** with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement is not considered appropriate if **ANY** of the following is **TRUE**⁹:

- ◆ The patient has an asymptomatic hiatal hernia and no objective evidence of GERD or GERD complications; **OR**
- ◆ The patient does not meet the criteria as outlined above; **OR**
- ◆ The patient is scheduled for open surgery for hiatal hernia repair, including **ANY** of the following:
 - 90° anterior partial fundoplication; **OR**
 - Hill repair.

Level of Care Criteria

Inpatient or outpatient.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43280	Laparoscopy, surgical, esophagogastric fundoplasty (e.g., Nissen, Toupet procedures)
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Daly et al. (2024) conducted systematic reviews to evaluate (i) surgical treatment of asymptomatic hiatal hernia versus surveillance, (ii) the use of mesh versus not, (iii) performing a fundoplication versus no fundoplication; and (iv) Roux-en-Y gastric bypass (RYGB) versus repeat fundoplication for recurrent hiatal hernia, with the aim of providing guidance regarding surgical decision making in the treatment of hiatal hernia. The expert panel suggested that select asymptomatic patients may be offered surgical repair when objective evidence exists of reflux or micro-aspiration or when patients are at high-risk for complications of micro-aspiration even in the absence of objective findings, such as lung transplant patients. The panel also suggested that conversion to RYGB for the management of recurrent hiatal hernia may be appropriate in certain patients without obesity and with recurrent type II, III, or IV hiatal hernia. The evidence for the routine use of mesh in hiatal hernia repair was inconclusive and the panel did not make a recommendation in this regard.⁴

Bhatt et al. (2023) systematically reviewed the perioperative outcomes of robotic and laparoscopic paraesophageal hernia (PEH) repair. Robotic surgery for large PEHs may offer benefits over standard laparoscopic approaches in decreasing conversion rates and duration of hospital stay. Some studies found a decrease in the need for esophageal lengthening procedures and fewer long-term recurrences. The perioperative complication rate is similar between the two techniques in most studies; however, one large study of nearly 170,000 patients in the early years of robotics adoption demonstrated a higher rate of esophageal perforation and respiratory failure in the robotic group (2.2% increase in absolute risk). Cost is another disadvantage of robotic repair when compared to laparoscopic repair. Limitations of this systematic review include the non-randomized and retrospective nature of the studies.¹³

Geerts et al. (2023) reviewed the anatomic location of hiatal hernia recurrences to assess the high rates of recurrence despite mesh reinforcement. A retrospective analysis of video clips from the procedure in 54 patients who underwent revision hiatal hernia surgery revealed that the left-anterior quadrant of the esophageal hiatus was involved in 43 patients

(80%), the right-anterior quadrant in 21 patients (39%), the left-posterior quadrant in 21 patients (39%), and the right-posterior quadrant in 10 patients (19%). Based on these findings, the authors hypothesized that both posterior and anterior hiatal reinforcement might lower the recurrence rate of hiatal hernia.³

Analatos et al. (2020) report the results of a randomized, double-blind clinical trial (NCT04436159) that compares clinical outcomes and postoperative mechanical complications of para-oesophageal hernia repair employing total (Nissen) versus posterior partial (Toupet) fundoplication in 70 patients who had undergone hernia reduction and crural repair. Ogilvie dysphagia scores were stable at the 3- and 6-month follow-up in the Nissen group but significantly improved in the Toupet group at 6 months. At 6 months, Dakkak dysphagia scores were significantly higher in the Nissen group than in the Toupet group. Although quality of life (QoL) scores improved throughout the follow-up, at 3 and 6 months postoperatively, the absolute median improvement in the mental component of the QoL questionnaire was significantly higher in the Toupet group. At 6 months, radiologically confirmed recurrence of hernias occurred in 46% of patients in the Nissen group and 47% of patients in the Toupet group. Based on these findings, the authors conclude Toupet fundoplication shows reduced obstructive complications and improved QoL compared with Nissen fundoplication following para-oesophageal hernia repair.¹⁴

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Clinical Guideline Revision History/Information

Original Date: December 19, 2024		
Review History		



Cohere Medical Policy – Laparoscopic Hiatal Hernia Repair and Anti-GERD Surgical Treatments

Clinical Guidelines for Medical Necessity Review

Version: 2
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Important Notices

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Guideline Information:

Specialty Area: Gastroenterology

Guideline Name: Cohere Medical Policy – Laparoscopic Hiatal Hernia Repair and Anti-GERD Surgical Treatments

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Medical Necessity Criteria

Service: Laparoscopic Hiatal Hernia Repair and Anti-GERD Surgical Treatments

Recommended Clinical Approach

Hiatal hernia (HH) is a common structural defect of the diaphragm that occurs when the anterior stomach (fundus) protrudes through the opening where the esophagus passes from the thorax to the abdomen (diaphragmatic hiatus). HH may be asymptomatic or accompanied by gastroesophageal reflux disease (GERD) and is usually diagnosed through a barium swallow test or diagnostic imaging. HH are classified into 4 types. In type I (sliding hiatal hernia), the gastroesophageal junction (GEJ) moves headward through the hiatus into the thorax. In type II (paraesophageal hernia), the gastric fundus herniates through the hiatus into the thorax, but the GEJ remains in the abdomen. Type III is a combination of types I and II, where the GEJ and stomach herniate into the thorax. Type IV is a type III HH with herniation of other organs into the thorax, such as the colon and spleen.¹ The 3 dominant pathogenic theories for HH include: (1) intra-abdominal pressure forces the GEJ into the thorax; (2) esophageal shortening displaces the GEJ into the thorax; and (3) GEJ migrates into the chest due to a widening of the diaphragmatic hiatus due to molecular and cellular changes.²

Treatment for HH is directed at symptoms of GERD, if present. Symptomatic HH (types II-IV) may require repair using a transabdominal or transthoracic approach. Initial or revision laparoscopic HH repair may also be medically necessary during bariatric surgery. A single laparoscopic HH repair is sufficient for most patients. Laparoscopic repair with suturing of the hiatal pillars followed by fundoplication is the standard medical practice for HH. Mesh reinforcement, commonly located at the posterior esophageal hiatus, is commonly used to lower recurrence rates.³ Additionally, fundoplication is used to repair paraesophageal HH and reduce the risk of postoperative gastrointestinal reflux as well as reinforce the repair to prevent recurrence. Laparoscopic esophagogastric fundoplasty is a procedure that involves

wrapping the upper part of the stomach around the lower part of the esophagus.¹ Physicians may choose this procedure for patients with gastroesophageal reflux. Laparoscopic HH surgery is generally not considered appropriate for patients with asymptomatic HH without objective evidence or a high risk of reflux or micro-aspiration.⁴

Medical Necessity Criteria

Indications

→ **Anti-reflux surgical treatment for GERD or laparoscopic hiatal hernia repair** are considered appropriate if **ANY** of the following is **TRUE**:

◆ **Anti-reflux surgery** (fundoplication [(e.g., Dor, Nissen, or Toupet procedures)], WITH or WITHOUT hiatal hernia repair (types 1-4), is considered appropriate with **ALL** of the following^{16,17}:

- **ANY** of the following:

- Without hiatal hernia repair (fundoplication only) with **ANY** of the following:

- ◆ Gastroesophageal reflux symptoms or GERD complications (e.g., reflux esophagitis) not fully responsive to medical treatment (e.g., unsuccessful treatment with proton pump inhibitors (PPIs), histamine receptor antagonists, or antacids, for at least 3 successive months under the direction of a healthcare professional)⁸; **OR**

- ◆ Gastroesophageal reflux symptoms present when medical treatment is contraindicated (e.g., intolerant or allergic to PPIs and/or histamine receptor antagonists); **OR**

- ◆ The patient has **ANY** of the following⁴:

- Documented evidence of micro-aspiration; **OR**
- High risk for complications of micro-aspiration (e.g., lung transplant recipient); **OR**

- With hiatal hernia (fundoplication with hiatal hernia repair) with **ANY** of the following:

- ◆ Gastroesophageal reflux symptoms or GERD complications (e.g., reflux esophagitis) not fully

- responsive to medical treatment (e.g., unsuccessful treatment with proton pump inhibitors (PPIs), histamine receptor antagonists, or antacids, for at least 3 successive months under the direction of a healthcare professional)⁶; **OR**
- ◆ Gastroesophageal reflux symptoms present when medical treatment is contraindicated (e.g., intolerant or allergic to PPIs and/or histamine receptor antagonists); **OR**
- ◆ The patient has any hiatal hernia with **ANY** of the following⁴:
 - Documented evidence of micro-aspiration; **OR**
 - High risk for complications of micro-aspiration (e.g., lung transplant recipient); **AND**
- **ALL** of the following objective criteria are met¹⁸:
 - High-resolution manometry or barium esophagram rules out achalasia; **AND**
 - **ANY** of the following that confirms GERD (abnormal esophageal acid exposure):
 - ◆ Upper endoscopy (e.g., in the form of reflux esophagitis, peptic stricture, or Barrett's esophagus); **OR**
 - ◆ Ambulatory esophageal pH-metry; **OR**
 - ◆ Ambulatory esophageal pH-impedance testing; **OR**
- ◆ **Laparoscopic hiatal hernia repair** with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement is considered appropriate if **ALL** of the following are **TRUE**¹⁻¹²:
 - Hiatal hernia is confirmed by **ANY** of the following⁵:
 - Cross-sectional imaging (CT or MRI); **OR**
 - Contrast radiography (barium esophagram or upper GI series); **OR**
 - Esophagogastroduodenoscopy (EGD); **OR**
 - Esophageal manometry; **OR**

- Detection during preoperative workup for bariatric surgery^{8,15}; **AND**
- Hiatal hernia is designated as type 2, 3, or 4 and is associated with **ANY** of the following symptoms:
 - Acute rotation of the stomach (gastric volvulus), including but not limited to upside-down stomach (UDS)¹; **OR**
 - Gastric outlet obstruction caused by the hernia; **OR**
 - Suspected or documented gastric strangulation; **OR**
 - Dysphagia or post-prandial fullness resulting from hernia-related mass effect and extrinsic compression on the lower esophagus¹⁵; **OR**
 - Persistent anemia when other causes have been excluded; **OR**
- ◆ **Revision** of prior hiatal hernia repair or fundoplication is considered appropriate if **ALL** of the following are true:
 - Evidence of failure of prior operation, including but not limited to recurrent hernia or migration of fundoplasty; **AND**
 - Recurrent symptoms (e.g., any of the symptoms described above for initial procedure) or recurrent GERD symptoms that are refractory despite adequate trial of medical therapy with PPI and/or histamine antagonist and/or antacids.

Non-Indications

→ **Anti-reflux surgical treatment for GERD or laparoscopic hiatal hernia repair** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ **Laparoscopic hiatal hernia repair** with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement is not considered appropriate with **ANY**⁹:
 - The patient has an asymptomatic hiatal hernia and no objective evidence of GERD or GERD complications; **OR**
 - The patient does not meet the criteria as outlined above; **OR**
 - The request is for open surgery for hiatal hernia repair; **OR**
- ◆ **Magnetic sphincter augmentation (LINX Reflux Management System)** is not considered appropriate with **ANY** of the following:

- This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness; **OR**
- ◆ **TIF (Transoral Incisionless Fundoplication)** is not considered appropriate with **ANY** of the following:
 - This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Level of Care Criteria

Inpatient or outpatient.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43280	Laparoscopy, surgical, esophagogastric fundoplasty (e.g., Nissen, Toupet procedures)
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed

Medical Evidence

Daly et al. (2024) conducted systematic reviews to evaluate (i) surgical treatment of asymptomatic hiatal hernia versus surveillance, (ii) the use of mesh versus not, (iii) performing a fundoplication versus no fundoplication; and (iv) Roux-en-Y gastric bypass (RYGB) versus repeat fundoplication for recurrent hiatal hernia, with the aim of providing guidance regarding surgical decision making in the treatment of hiatal hernia. The expert panel suggested that select asymptomatic patients may be offered surgical repair when objective evidence exists of reflux or micro-aspiration or when patients are at high-risk for complications of micro-aspiration even in the absence of objective findings, such as lung transplant patients. The panel also suggested that conversion to RYGB for the management of recurrent hiatal hernia may be appropriate in certain patients without obesity and with recurrent type II, III, or IV hiatal hernia. The evidence for the routine use of mesh in hiatal hernia repair was inconclusive and the panel did not make a recommendation in this regard.⁴

Bhatt et al. (2023) systematically reviewed the perioperative outcomes of robotic and laparoscopic paraesophageal hernia (PEH) repair. Robotic surgery for large PEHs may offer benefits over standard laparoscopic approaches in decreasing conversion rates and duration of hospital stay. Some studies found a decrease in the need for esophageal lengthening procedures and fewer long-term recurrences. The perioperative complication rate is similar between the two techniques in most studies; however, one large study of nearly 170,000 patients in the early years of robotics adoption demonstrated a higher rate of esophageal perforation and respiratory failure in the robotic group (2.2% increase in absolute risk). Cost is another disadvantage of robotic repair when compared to laparoscopic repair. Limitations of this systematic review include the non-randomized and retrospective nature of the studies.¹³

Geerts et al. (2023) reviewed the anatomic location of hiatal hernia recurrences to assess the high rates of recurrence despite mesh reinforcement. A retrospective analysis of video clips from the procedure in 54 patients who underwent revision hiatal hernia surgery revealed that the left-anterior quadrant of the esophageal hiatus was involved in 43 patients

(80%), the right-anterior quadrant in 21 patients (39%), the left-posterior quadrant in 21 patients (39%), and the right-posterior quadrant in 10 patients (19%). Based on these findings, the authors hypothesized that both posterior and anterior hiatal reinforcement might lower the recurrence rate of hiatal hernia.³

Analatos et al. (2020) report the results of a randomized, double-blind clinical trial (NCT04436159) that compares clinical outcomes and postoperative mechanical complications of para-oesophageal hernia repair employing total (Nissen) versus posterior partial (Toupet) fundoplication in 70 patients who had undergone hernia reduction and crural repair. Ogilvie dysphagia scores were stable at the 3- and 6-month follow-up in the Nissen group but significantly improved in the Toupet group at 6 months. At 6 months, Dakkak dysphagia scores were significantly higher in the Nissen group than in the Toupet group. Although quality of life (QoL) scores improved throughout the follow-up, at 3 and 6 months postoperatively, the absolute median improvement in the mental component of the QoL questionnaire was significantly higher in the Toupet group. At 6 months, radiologically confirmed recurrence of hernias occurred in 46% of patients in the Nissen group and 47% of patients in the Toupet group. Based on these findings, the authors conclude Toupet fundoplication shows reduced obstructive complications and improved QoL compared with Nissen fundoplication following para-oesophageal hernia repair.¹⁴

Several new therapies exist for the treatment of GERD and/or hiatal hernia. The LINX system seeks to control reflux with the implantation of a ring of magnetic beads around the distal esophagus, thereby creating an artificial sphincter. Broadly known as magnetic sphincter augmentation, this novel procedure appears to be well-tolerated by many patients, but the long-term efficacy and safety profile is not yet known simply by virtue of its short time on the market. TIF, or transoral incisionless fundoplication, is meant to endoscopically treat GERD by forming a partial esophagogastric fundoplication, thereby limiting the inappropriate flow of gastric contents. Again, although the procedure appears to be well-tolerated, concerns remain as to the long-term safety and efficacy of the procedure. Because these novel therapies do not yet have long-term efficacy results, nor a diverse range of randomized, controlled, double-blinded trials of statistical rigor, it is premature to presume clinical outcomes and benefits, as well as long-term

safety. These procedures cannot be considered equivalent or superior to the existing standard of surgical care for the same reason.^{[19-22](#)}

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Clinical Guideline Revision History/Information

Original Date: December 19, 2024		
Review History		
Version 2	3/6/2025	• Created indications for fundoplication without hiatal hernia, previously absent from policy. • Clarified hiatal hernia repair criteria to ensure non-approval of asymptomatic type 1 HH (not medically appropriate). • Provided non-indications for LINX and TIF procedures, which are novel and not yet clinically proven or medically necessary. • Added references. • Added indications for revision, previously absent from policy. • Modified criteria to allow manometry of barium esophagram for r/o of achalasia.



Cohere Medical Policy – Laparoscopic Hiatal Hernia Repair

Clinical Guidelines for Medical Necessity Review

Version: 1.0
Effective Date: December 19, 2024

Important Notices

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Guideline Information:

Specialty Area: Gastroenterology

Guideline Name: Cohere Medical Policy – Laparoscopic Hiatal Hernia Repair

Date of last literature review: 12/05/2024

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Laparoscopic Hiatal Hernia Repair

Recommended Clinical Approach

Hiatal hernia (HH) is a common structural defect of the diaphragm and occurs when the anterior stomach (fundus) protrudes through the opening where the esophagus passes from the thorax to the abdomen (diaphragmatic hiatus). HH may be asymptomatic or accompanied by gastroesophageal reflux disease (GERD) and is usually diagnosed through a barium swallow test or diagnostic imaging. HH are classified into 4 types. In type I (sliding hiatal hernia), the gastroesophageal junction (GEJ) moves headward through the hiatus into the thorax. In type II (paraesophageal hernia), the gastric fundus herniates through the hiatus into the thorax, but the GEJ remains in the abdomen. Type III is a combination of types I and II, where the GEJ and stomach herniate into the thorax. Type IV is a type III HH with herniation of other organs into the thorax, such as the colon and spleen.¹ The 3 dominant pathogenic theories for HH include: (1) intra-abdominal pressure forces the GEJ into the thorax; (2) esophageal shortening displaces the GEJ into the thorax; and (3) GEJ migrates into the chest due to a widening of the diaphragmatic hiatus due to molecular and cellular changes.²

Treatment for HH is directed at symptoms of GERD, if present. Symptomatic HH (types II–IV) may require repair using a transabdominal or transthoracic approach. Initial or revision laparoscopic HH repair may also be medically necessary during bariatric surgery. A single laparoscopic HH repair is sufficient for most patients. Laparoscopic repair with suturing of the hiatal pillars followed by fundoplication is the standard medical practice for HH. Mesh reinforcement, commonly located at the posterior esophageal hiatus, is commonly used to lower recurrence rates.³ Additionally, fundoplication is used to repair paraesophageal HH and reduce the risk of postoperative gastrointestinal reflux as well as reinforce the repair to prevent recurrence. Laparoscopic esophagogastric fundoplasty is a procedure that involves wrapping the upper part of the stomach around the lower part of the esophagus.¹ Physicians may choose this procedure for patients with gastroesophageal reflux. Laparoscopic HH surgery is generally not considered appropriate for patients with asymptomatic HH without objective evidence or a high risk of reflux or micro-aspiration.⁴

Medical Necessity Criteria

Indications

→ **Laparoscopic hiatal hernia repair** with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement is considered appropriate if **ALL** of the following are **TRUE**¹⁻¹²:

◆ Hiatal hernia is confirmed by **ANY** of the following⁵:

- Diagnostic imaging; **OR**
 - Radiology; **OR**
 - Esophagogastroduodenoscopy (EGD); **OR**
 - Manometry; **OR**
 - Detection during preoperative workup for bariatric surgery¹⁵;
- AND**

◆ **ANY** of the following is **TRUE**:

- Acute rotation of the stomach (gastric volvulus), including but not limited to upside down stomach (UDS)¹; **OR**
- Gastric outlet obstruction caused by the hernia; **OR**
- Suspected or documented gastric strangulation; **OR**
- Dysphagia or post-prandial fullness resulting from hernia-related mass effect and extrinsic compression on the lower esophagus¹⁵; **OR**
- Gastroesophageal reflux symptoms or GERD complications (e.g., reflux esophagitis) not fully responsive to medical treatment (e.g., unsuccessful treatment with proton pump inhibitors (PPIs), histamine receptor antagonists, or antacids, for at least 3 successive months under the direction of a healthcare professional)⁶; **OR**
- Gastroesophageal reflux symptoms present when medical treatment is contraindicated (e.g., intolerant or allergic to PPIs and/or histamine receptor antagonists); **OR**
- Persistent anemia when other causes have been excluded; **OR**
- The patient has an asymptomatic hiatal hernia and **ANY** of the following⁴:
 - Documented evidence of gastro-esophageal reflux (e.g., EGD evidence of reflux esophagitis or Barrett's esophagus, or abnormal parameters on ambulatory pH or impedance monitoring); **OR**

- Documented evidence of micro-aspiration; **OR**
- High risk for complications of micro-aspiration (e.g., lung transplant recipient); **OR**
- Detection during bariatric surgery.^{8,15}

Non-Indications

→ **Laparoscopic hiatal hernia repair** with or without fundoplication (e.g., Dor, Nissen, or Toupet procedures) and/or mesh placement is not considered appropriate if **ANY** of the following is **TRUE**⁹:

- ◆ The patient has an asymptomatic hiatal hernia and no objective evidence of GERD or GERD complications; **OR**
- ◆ The patient does not meet the criteria as outlined above; **OR**
- ◆ The patient is scheduled for open surgery for hiatal hernia repair, including **ANY** of the following:
 - 90° anterior partial fundoplication; **OR**
 - Hill repair.

Level of Care Criteria

Inpatient or outpatient.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43280	Laparoscopy, surgical, esophagogastric fundoplasty (e.g., Nissen, Toupet procedures)
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Medical Evidence

Daly et al. (2024) conducted systematic reviews to evaluate (i) surgical treatment of asymptomatic hiatal hernia versus surveillance, (ii) the use of mesh versus not, (iii) performing a fundoplication versus no fundoplication; and (iv) Roux-en-Y gastric bypass (RYGB) versus repeat fundoplication for recurrent hiatal hernia, with the aim of providing guidance regarding surgical decision making in the treatment of hiatal hernia. The expert panel suggested that select asymptomatic patients may be offered surgical repair when objective evidence exists of reflux or micro-aspiration or when patients are at high-risk for complications of micro-aspiration even in the absence of objective findings, such as lung transplant patients. The panel also suggested that conversion to RYGB for the management of recurrent hiatal hernia may be appropriate in certain patients without obesity and with recurrent type II, III, or IV hiatal hernia. The evidence for the routine use of mesh in hiatal hernia repair was inconclusive and the panel did not make a recommendation in this regard.⁴

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Cohere Medicare Advantage Policy – Home Health Speech Therapy

Clinical Guidelines for Medical Necessity Review

Version: 1
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Important Notices

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Medical Necessity Criteria

Service: Home Health Speech Therapy

Benefit Category

None.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁴

- [Local Coverage Determination \(LCD\). Home health speech-language pathology \(L34563\)](#)
- [Local Coverage Determination \(LCD\). Home health-surface electrical stimulation in the treatment of dysphagia \(L34565\)](#)
- [Billing and Coding. Speech-Language Pathology \(A52866\)](#)
- [Billing and Coding. Home health speech-language pathology \(A53052\)](#)

Recommended Clinical Approach

Treatment requires the judgment, knowledge, and skills of a licensed and certified speech-language pathologist who meets generally accepted standards of practice and is targeted and effective in treating the individual's diagnosed impairment or condition. Treatment is expected to produce clinically significant and measurable improvement in the member's level of functioning within a medically reasonable period of time; alternatively, the treatment is part of a medically necessary program to prevent significant functional regression.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of home health speech therapy. This process helps to prevent both incorrect denials and inappropriate approvals

of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Speech therapy provided in the home setting allows those who live in rural areas to access care when traveling far distances is difficult.
- Feltner et al. (2024) conducted a systematic review of published guidance from the United States Preventive Services Task Force (USPSTF) on screening for speech and language delay and disorders in children aged 5 and younger. There were no identified harms of screening or interventions.⁵
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Patients who receive speech therapy in a home setting report improved patient outcomes due to being in a familiar environment.
- Improved communication. Research shows that therapy benefits those with primary and secondary speech and language disorders. This includes hearing or neurological impairment, as well as developmental, behavioral, and emotional difficulties.⁶ Expanded vocabulary and grammar and enhanced articulation and phonetics are noted benefits of therapy.
- Social and emotional development. Arts et al. (2022) noted that adolescents with developmental language delay had improved social-emotional functioning. Therapy consisted of “linguistics, social communication (pragmatic) skills, and cognitive components.” The authors noted that skills should be taught through social dialogue with other individuals.⁷
- Improved academic performance and school readiness. The benefits of therapy include aiding the student “to understand and comply with the behavioral demands of school” and developing oral language skills to facilitate a foundation for early reading success.⁸
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Home speech therapy** is considered appropriate if **ALL** of the following are **TRUE**:

◆ **ANY** of the following⁹⁻¹²:

- In order to leave the home, the patient requires the help of another person or medical equipment such as crutches, a walker, or a wheelchair; **OR**
- Receiving medical services outside the home would expose the patient to substantial medical risk; **AND**

◆ It is difficult for the patient to leave the home and they typically cannot do so (e.g., the patient is considered homebound)*; **AND**

◆ After the patient begins receiving home healthcare, a physician evaluates and recertifies the plan of care (POC) every 60 days including **ALL** of the following^{13,14}:

- Short- and long-term goals with documentation on how goals will be obtained; **AND**
- An estimated time of when goals will be attained; **AND**
- Measurable objectives; **AND**
- The number of visits requested is appropriate for the diagnosis; **AND**
- Therapy interventions to be used; **AND**

◆ The service is inherently complex such that it can only be safely and effectively performed by a qualified technical or professional health personnel such as a registered nurse, a licensed practical

(vocational) nurse, a respiratory therapist, or other skilled staff acting within the applicable scope of practice for the jurisdiction where services are provided, allowing for care rendered under the direct supervision of ancillary speech/language pathologist as permitted under state law(s); **AND**

◆ Symptoms with **ANY** of the following:

- Changes following a period of chronic or stable symptoms; **OR**
- Recent diagnosis; **AND**

◆ **ANY** of the following:

- Treatment is for **ANY** of the following:

- Aphasia^{1,15-20}; **OR**
- Acquired apraxia²¹; **OR**
- Cognitive-communication disorders; **OR**
- Developmental language or speech disorders* as evidenced by **ANY** of the following^{1,22,23}:

◆ A speech disorder with impairment of **ANY** of the following:

- Sound production (e.g., articulation, phonological process, apraxia, dysarthria); **OR**
- Fluency (e.g., stuttering, cluttering); **OR**
- Voice; **OR**

◆ A language disorder with impaired comprehension and/or use of spoken, written and/or other symbol systems (e.g., the form of language [phonology, morphology, syntax], the content of language [semantics], and/or the function of language in communication [pragmatics] in any combination); **OR**

- Dysarthria²⁴; **OR**
- Dysphagia^{1,13,25}; **OR**
- Voice disorders including **ANY** of the following²⁶:

◆ Physiological voice disorders that result from alterations in respiratory, laryngeal, or vocal tract mechanisms; **OR**

◆ Organic voice disorders that result from **ANY** of the following:

- Physical changes in the vocal mechanism, such as alterations in vocal fold tissues (e.g., edema or vocal nodules) and/or structural changes in the larynx due to aging; **OR**
 - Problems with the central or peripheral nervous system innervation to the larynx that affect the functioning of the vocal mechanism (e.g., vocal tremor, spasmodic dysphonia, or vocal fold paralysis); **OR**
- ◆ Voice disorders that result from inefficient use of the vocal mechanism when the physical structure is normal (e.g., vocal fatigue, muscle tension dysphonia or aphonia, diplophonia, or ventricular phonation); **OR**
- **ANY** of the following services:
 - Screening of **ANY** of the following²⁷:
 - ◆ Speech; **OR**
 - ◆ Language; **OR**
 - ◆ Dysphagia; **OR**
 - Re-evaluation with **ALL** of the following³:
 - ◆ Progress is expected if therapy resumes; **AND**
 - ◆ Documentation supports the need for further tests and measurements after the initial evaluation; **AND**
 - ◆ Indications for a re-evaluation include **ANY** of the following new clinical findings:
 - A significant change in the patient's condition; **OR**
 - Failure to respond to the therapeutic interventions outlined in the plan of care; **OR**
 - The patient is being discharged and **ANY** of the following:
 - To determine whether goals have been met; **OR**

- For the use of the physician or the treatment setting at which treatment will be continued; **OR**
- Continued coverage when the patient meets **ALL** of the following:
 - ◆ Compliant and active in therapy; **AND**
 - ◆ Demonstrates significant improvement that will benefit long-term therapy goals; **AND**
 - ◆ Functional progress is demonstrated; **AND**
 - ◆ Skills are being utilized in the patient's natural environment; **AND**
 - ◆ Re-evaluation is completed annually (every 12 months) to confirm progress and level of function to necessitate continuation of therapy; **AND**
 - ◆ Deficiencies are identified by comparing results from previous evaluations with more recent results; **AND**
 - ◆ Therapy goals are unmet and additional therapy is medically necessary; **OR**
- Therapeutic services related to the use of a non-speech generating device (SGD) for **ANY** of the following¹:
 - ◆ Programming of a device; **OR**
 - ◆ Modification of a device; **OR**
 - ◆ Services for a patient who is non-verbal or does not have the capacity for verbal communication; **OR**
 - ◆ Development of operational competence in using an SGD or aids (e.g., customizing features of the device to meet specific communication needs); **OR**
- Auditory rehabilitation following cochlear implant (including hearing and therapeutic services with or without speech processor programming performed by an audiologist) and **ANY** of the following¹:
 - ◆ Extensive auditory rehabilitation therapy that focuses on audition, cognition, language, and

- speech skills (including suprasegmental aspects) to improve the patient's ability to discriminate and exhibit improvements in speech (e.g., manner, place, and voicing); **OR**
 - ◆ Family member or caregiver training for auditory verbal techniques; **OR**
- ◆ **ANY** of the following services:
 - Speech/hearing treatment and follow-up include **ALL** of the following¹:
 - The patient has **ANY** of the following:
 - ◆ Speech disorder; **OR**
 - ◆ Articulation disorder; **OR**
 - ◆ Fluency and voice disorders; **OR**
 - ◆ Language skills disorder; **OR**
 - ◆ Cognitive aspects of communication; **AND**
 - Service(s) requested include **ANY** of the following:
 - ◆ Consulting or counseling, including necessary referrals; **OR**
 - ◆ Training and support to family members/caregivers and other communication partners of the patient; **OR**
 - ◆ Developing and establishing effective augmentative and alternative communication techniques and strategies as indicated by the patient's State for selecting, prescribing, and dispensing aids and devices; **OR**
 - ◆ Selecting, fitting, and establishing effective use of appropriate prosthetic/adaptive devices for speaking; **OR**
 - ◆ Providing aural rehabilitation and related counseling services to patients with hearing loss and to their family members/caregivers; **OR**
 - ◆ Providing interventions for central auditory processing disorders; **OR**
 - Re-evaluation for **ALL** of the following³:
 - Progress is expected if therapy resumes; **AND**

- Documentation supports the need for further tests and measurements after the initial evaluation; **AND**
- Indications for a re-evaluation include **ANY** of the following new clinical findings:
 - ◆ A significant change in the patient's condition; **OR**
 - ◆ Failure to respond to the therapeutic interventions outlined in the plan of care; **OR**
 - ◆ The patient is being discharged and **ANY** of the following:
 - To determine whether goals have been met; **OR**
 - For the use of the physician or the treatment setting at which treatment will be continued; **OR**
- Continued coverage when the patient meets **ALL** of the following:
 - Compliant and active in therapy; **AND**
 - Demonstrates significant improvement that will benefit long-term therapy goals; **AND**
 - Functional progress is demonstrated; **AND**
 - Skills are being utilized in the patient's natural environment; **AND**
 - Re-evaluation is completed annually (every 12 months) to confirm progress and level of function to necessitate continuation of therapy; **AND**
 - Deficiencies are identified by comparing results from previous evaluations with more recent results; **AND**
 - Therapy goals are unmet and additional therapy is medically necessary; **OR**
- SGDs or aids for **ANY** of the following¹:
 - To supplement oral speech; **OR**
 - To assess the need for continued use; **OR**
 - To identify the need for changes in objectives; **OR**
- As indicated by State regulations where the patient is receiving care when the professional assessment of a clinician indicates a significant improvement, decline, or change in the patient's condition or functional status that

was not anticipated in the plan of care for **ANY** of the following:

- Speech fluency; **OR**
- Sound production; **OR**
- Speech sound production with evaluation of language comprehension and expression; **OR**
- Behavioral and qualitative analysis of voice and resonance; **OR**
- Evaluation of abilities of cognitive (executive) function (e.g., assessment of learning abilities, memory and working memory, abstract thought, language, and attention) using standardized cognitive performance testing¹; **OR**
- Behavioral and qualitative analysis of voice and resonance disorders (e.g., dysphonia, aphonia, laryngospasm, dystonia, hypernasality, hyponasality)¹; **OR**
- Developmental testing (including assessment, interpretation, and a report of motor, language, social, adaptive and/or cognitive functioning by standardized developmental instruments)¹; **OR**
- Neurobehavioral status exam (including assessment, interpretation, and a report) to assess thinking, reasoning and judgment¹; **OR**
- Speech/aural rehabilitation following cochlear ear implant (with or without speech processor programming**) when therapy includes **ANY** of the following¹:
 - Focus on audition, cognition, language, and speech skills; **OR**
 - Training of auditory verbal techniques for family members or caregivers; **OR**
 - Expected improvement of auditory skills pertaining to the suprasegmental aspects; **OR**
 - Expected improvement of the patient's ability to discriminate and exhibit improvements in speech (e.g., manner, place, and voicing); **OR**
- Oral function therapy¹; **OR**
- Voice prosthetic modification and training (including programming or reprogramming the device to meet the patient's needs)¹; **OR**

- Therapeutic exercises and activities to strengthen muscles (e.g., jaw, tongue, facial) and improve functional performance¹; **OR**
- Cognitive skills development including informal assessment/observation of cognitive abilities necessary for performing daily activities (e.g., alertness, orientation, attention, memory, problem-solving, recall, affect, reasoning, judgment, organization, and retention)¹; **OR**
- Sensory integrative techniques for oral sensory stimulation to develop adaptive skills for sensory processing¹; **OR**
- Self-care/home management training (e.g., compensatory training, meal preparation, safety procedures, and instructions in the use of assistive technology devices/adaptive equipment).¹

* NOTE: Even if a patient is homebound, they can still leave the home for medical treatment, religious services, or to attend an adult day care center without putting their homebound status at risk. Leaving home for short periods of time or for special non-medical events, such as a family reunion, funeral, or graduation, should also not affect homebound status. The patient may also take occasional trips to the barber or beauty parlor.

** NOTE: Speech processor programming is usually performed by an audiologist.

Non-Indications

→ **Home speech therapy** is not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ State-specific criteria do not allow coverage; **OR**
- ◆ Aphasia, excluding disorders associated with primary sensory, general mental deterioration or psychiatric disorders by standardized or informal measures¹; **OR**
- ◆ Services are custodial in nature (i.e., nonmedical services to assist with daily living and independence)²⁸; **OR**

- ◆ Services are solely requested for the comfort or convenience of the caregiver or family member versus the medical necessity of the patient²⁹; **OR**
- ◆ **ANY** of the following procedures:
 - Non-diagnostic, non-therapeutic, routine, repetitive, and reinforcing (e.g., practicing word drills without skilled feedback)³⁰; **OR**
 - Repetitive and/or that reinforce previously learned material³⁰; **OR**
 - Procedures which may be effectively carried out with the patient by a non-professional (e.g., family, restorative aide) after instruction is completed³⁰; **OR**
 - Laryngoscopy for medical diagnostic purposes performed by a non-physician³⁰; **OR**
- ◆ **ANY** of the following services³⁰:
 - For chronic disorders of memory and orientation without significant functional progress; **OR**
 - Supervision of the use of memory aids (e.g., memory books, memory boards, or communication books); **OR**
 - Provided by a non-licensed SLP (e.g., SLP assistant or aide); **OR**
 - Provision of practice for use of augmentative or alternative communication systems after being taught their use; **OR**
- ◆ **ANY** of the following disorders^{30,31}:
 - Fluency disorder; **OR**
 - Conceptual handicap; **OR**
 - Dysprosody; **OR**
 - Stuttering and cluttering (except neurogenic stuttering caused by acquired brain damage); **OR**
 - Myofunctional disorders (e.g., tongue thrust).

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description

G0153	Services performed by a qualified speech-language pathologist in the home health or hospice setting, each 15 minutes
G0161	Services performed by a qualified speech-language pathologist, in the home health setting, in the establishment or delivery of a safe and effective speech-language pathology maintenance program, each 15 minutes
S9128	Speech therapy, in the home, per diem

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Definitions

Restorative/Rehabilitative therapy – Skilled therapy must be reasonably expected to improve the patient’s functional capacity or adaptation to impairments in order to be covered.¹

Maintenance Therapy – Even if no improvement is expected, under the skilled nursing facility (SNF), home health (HH), and outpatient (OPT) coverage standards, skilled therapy services are covered when an individualized assessment of the patient’s condition demonstrates that skilled care is necessary for the performance of a safe and effective maintenance program to maintain the patient’s current condition or prevent or slow further deterioration. Skilled maintenance therapy may be covered when the particular patient’s special medical complications or the complexity of the therapy procedures require skilled care.¹

Maintenance Program – Coverage of therapy services, including speech-language pathology services, for a maintenance program based on the patient’s need for skilled care in that maintenance program as described in the CMS Internet-Only Manual, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 7, §40.2.1.¹

Re-evaluation – A re-evaluation would be considered reasonable and necessary for indications described by the CMS Internet-Only Manual, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 7, §40.2.3.¹

Medical Evidence

Mormer et al. (2024) analyzed racial disparities and the utilization of speech therapy by individuals diagnosed with oropharyngeal dysphagia. Of 56,198 identified individuals, 60.7% (n = 34,112) received speech therapy (61.5% White, 15.6% Black, 13.1% Other, and 9.8% Hispanic). Racial disparities were noted, particularly among those who were admitted to the hospital with acute stroke or pneumonia. A significant difference was not identified among patients with bacterial pneumonia or sepsis. The study is one of the few that addresses racial disparities – future research is needed with respect to the patient’s primary diagnosis, duration of therapy, and location of therapy.³²

Osman et al. (2023) performed a systematic review on the role of early initiation of speech therapy for autism spectrum disorder (ASD). A total of 501 participants were included (78% male, 22% female). The review demonstrated the benefits of early initiation – these include an increase in self-esteem, social skills, cognitive ability, and effective communication. Anxiety also decreased among the individual and those with whom they interact in daily life (e.g., family, caregivers, teachers). The research also highlights the necessity of educating parents and caregivers on how to identify red flags and effectively overcome challenges.³³

Sand et al. (2022) conducted a systematic review and meta-analysis of the benefits of speech therapy for individuals born with a cleft palate. Despite reconstructive surgery as a child, 50% of children continue to have speech difficulties that require additional surgery and speech therapy. Of the 34 studies that met the criteria for inclusion, 19 yielded data on 343 individuals. The studies analyzed language ability, speech production measurements, and self-reported outcomes. Overall, the results demonstrate a significant improvement in speech production following speech therapy, especially among younger children.³⁴

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Clinical Guideline Revision History/Information

Original Date: April 10, 2025		
Review History		

Cohere Medical Policy – Home Speech Therapy

Clinical Policy for Medical Necessity Review

CHP-088-2 Version 2

Cohere UMC Approval Date: April 21, 2026

Last Annual Review: April 21, 2026

Revision Date: Not applicable

Next Annual Review: April 21, 2027

Specialty: Home Health

Population Type: Adult (18+ years old), Pediatric (0-17 years old)

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Procedure Codes (CPT/HCPCS)

Service: Home Speech Therapy	
Code	Description
G0153	Services performed by a qualified speech-language pathologist in the home health or hospice setting, each 15 minutes
G0161	Services performed by a qualified speech-language pathologist, in the home health setting, in the establishment or delivery of a safe and effective speech-language pathology maintenance program, each 15 minutes
S9128	Speech therapy, in the home, per diem

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Service: Home Speech Therapy - Description

Speech-language pathology (SLP) services involve evaluating, diagnosing, and treating speech, language, cognitive-communication, and swallowing disorders using standardized tests and specialized instruments.¹ Interventions may include augmentative and alternative communication, swallowing exercises, laryngeal adduction training, and compensatory techniques.¹ Treatment is expected to produce clinically significant and measurable improvement in functioning or to prevent significant functional regression.¹

Service: Home Speech Therapy - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Indications

- **Home speech therapy** is considered appropriate if **ALL** of the following are **TRUE**:
 - Home confinement due to **ALL** of the following^{2,3}:
 - Leaving the home is difficult and requires significant effort; **AND**
 - Medical condition(s) make it so the patient is unable to leave the home regularly; **AND**
 - **ANY** of the following:
 - Help of another person, medical equipment (e.g., cane, crutches, walker, wheelchair), or special transportation is required to leave home; **OR**
 - Leaving the home is medically contraindicated; **AND**
 - Services are provided by a licensed speech/language pathologist, including for care rendered under the direct supervision of an ancillary speech/language pathologist as permitted under state law(s)¹; **AND**
 - Amount, frequency, and duration of treatments are appropriate for the patient and diagnosis¹; **AND**
 - Plan of care (POC) includes **ALL** of the following¹:
 - Objective measures demonstrate the necessity for a course of therapy; **AND**
 - Reasonable expectation of recovery or improvement in function to support initiation or continuation of treatment; **AND**
 - Short-term and/or long-term treatment goals; **AND**
 - Specific therapy interventions to be used; **AND**
 - The number of visits requested is appropriate for the diagnosis; **AND**

- Treatment compliance (unless initial evaluation or screening); **AND**
- Symptoms with **ANY** of the following¹:
 - Changes following a period of chronic or stable symptoms; **OR**
 - Recent diagnosis; **AND**
- Treatment is for **ANY** of the following conditions:
 - Aphasia⁴⁻⁹; **OR**
 - Acquired apraxia¹⁰; **OR**
 - Cognitive-communication disorders¹¹; **OR**
 - Developmental language or speech disorders^{A, 12, 13}; **OR**
 - Dysarthria¹⁴; **OR**
 - Dysphagia¹⁵; **OR**
 - Fluency disorder in patients less than 18 years of age¹; **OR**
 - Fluency disorder caused by acquired brain damage in patients greater than or equal to 18 years of age¹; **OR**
 - Voice disorders, including functional voice disorders^B and organic voice disorders^{C, 16-18}; **AND**
- Treatment is for **ANY** of the following visit types:
 - Initial evaluation or screening¹; **OR**
 - Re-evaluation with **ALL** of the following¹:
 - ☐ Documentation supports the need for further testing or objective measurements after the initial evaluation; **AND**
 - ☐ Progress is expected if treatment continues; **AND**
 - ☐ **ANY** of the following new clinical findings:
 - ▲ Failure to respond to the therapeutic interventions outlined in the POC; **OR**
 - ▲ Significant change in the patient's condition; **OR**
 - ▲ The patient is being discharged, and re-evaluation is needed to determine how treatment will be continued in the home setting; **OR**
 - Continuation of care, with **ALL** of the following¹:
 - ☐ Deficiencies are identified and compared with previous evaluations; **AND**
 - ☐ Functional improvement demonstrates benefits toward treatment goals; **AND**
 - ☐ Re-evaluation is completed annually every 12 months to confirm progress and level of function to necessitate continuation of care; **AND**
 - ☐ Skills are being utilized in the patient's natural environment; **AND**
 - ☐ Therapy goals are unmet, and additional therapy is medically necessary; **AND**
 - ☐ Treatment compliance; **AND**
- Treatment is for **ANY** of the following services:
 - Auditory rehabilitation following cochlear implant and **ANY** of the following¹⁹:
 - ☐ Extensive auditory rehabilitation therapy that focuses on audition, cognition, language, and speech skills (including suprasegmental aspects) to improve the patient's ability to discriminate and exhibit improvements in speech (e.g., manner, place, and voicing); **OR**
 - ☐ Hearing and therapeutic services with or without speech processor programming performed by an audiologist; **OR**
 - ☐ Family member or caregiver training for auditory verbal techniques; **OR**
 - Evaluation of laryngeal function (e.g., aerodynamic testing and acoustic testing)¹; **OR**
 - Fluoroscopic evaluation of swallowing function¹; **OR**

- Speech or language rehabilitation or maintenance; **OR**
- Therapeutic services related to cognitive function¹; **OR**
- Use of a non-speech generating device (non-SGD) for **ANY** of the following²⁰:
 - Development of operational competence in using a non-SGD or aid; **OR**
 - Programming, modifying, or customizing a device; **OR**
 - The patient is non-verbal or does not have the capacity for verbal communication.

Non-Indications

- **Home speech therapy** is not considered appropriate if **ANY** of the following is **TRUE**:
 - The request is for nonmedical services to assist with daily living and independence²¹; **OR**
 - The request is for the comfort or convenience of the caregiver or family member versus the medical necessity of the patient²²; **OR**
 - State-specific criteria do not allow coverage.¹

Definitions and Notes

^ADevelopmental language or speech disorder – Characterized by impaired articulation of speech sounds, fluency, or voice, or impaired comprehension and/or use of spoken, written and/or other symbol systems (e.g., the form of language [phonology, morphology, syntax], the content of language [semantics], and/or the function of language in communication [pragmatics] in any combination).^{16,17}

^BFunctional voice disorder – Characterized by alterations in respiratory, laryngeal, or vocal tract mechanisms, or has resulted from inefficient use of the vocal mechanism when the physical structure is normal (e.g., vocal fatigue, muscle tension dysphonia or aphonia, diplophonia, or ventricular phonation).^{16,17}

^COrganic voice disorder – Characterized by physical changes in the vocal mechanism, such as alterations in vocal fold tissues (e.g., edema or vocal nodules) and/or structural changes due to aging or problems with the central or peripheral nervous system innervation to the larynx that affect the functioning of the vocal mechanism (e.g., vocal tremor, spasmodic dysphonia, or vocal fold paralysis).^{17,18}

Medical Evidence

Mormer et al. (2024) analyzed racial disparities and the utilization of speech therapy by individuals diagnosed with oropharyngeal dysphagia. Of 56,198 identified individuals, 60.7% (n = 34,112) received speech therapy (61.5% White, 15.6% Black, 13.1% Other, and 9.8% Hispanic). Racial disparities were noted, particularly among those who were admitted to the hospital with acute stroke or pneumonia. A significant difference was not identified among patients with bacterial pneumonia or sepsis. The study is one of the few that addresses racial disparities - future research is needed with respect to the patient's primary diagnosis, duration of therapy, and location of therapy.²³

Sackley et al. (2024) performed a randomized controlled trial to evaluate the effectiveness of two speech and language therapy (SLT) approaches—Lee Silverman Voice Treatment (LSVT LOUD) and routine NHS SLT—compared with no therapy for dysarthria in Parkinson's disease. A total of 388 participants with Parkinson's-related dysarthria were randomized in a 1:1:1 ratio. LSVT LOUD involved four 50-minute sessions per week for 4 weeks, supplemented by daily home practice. NHS SLT dosage and methods were therapist-determined and generally lower in intensity. The primary outcome was patient-reported Voice Handicap Index (VHI) score at 3 months, with follow-up at 6 and 12 months. At 3 months, the LSVT LOUD group reported significantly better outcomes, and NHS SLT showed no evidence of improvement compared with no therapy. Secondary outcomes also favored LSVT LOUD, with benefits in VHI emotional and functional subscales, communication-related quality of life, and dysarthria-specific measures, sustained over 12 months. Adverse events, mostly mild vocal strain, were more common with LSVT LOUD but were transient and manageable. The study concluded that LSVT LOUD is superior to both NHS SLT and no therapy in reducing the impact of dysarthria in Parkinson's disease.²⁴

Osman et al. (2023) performed a systematic review on the role of early initiation of speech therapy for autism spectrum disorder (ASD). A total of 501 participants were included (78% male, 22% female). The review demonstrated the benefits of early initiation - these include an increase in self-esteem, social skills, cognitive ability, and effective communication. Anxiety also decreased among the individual and those with whom they interact in daily life (e.g., family, caregivers, teachers). The research also highlights the necessity of educating parents and caregivers on how to identify red flags and effectively overcome challenges.²⁵

Sand et al. (2022) conducted a systematic review and meta-analysis of the benefits of speech therapy for individuals born with a cleft palate. Despite reconstructive surgery as a child, 50% of children continue to have speech difficulties that require additional surgery and speech therapy. Of the 34 studies that met the criteria for inclusion, 19 yielded data on 343 individuals. The studies analyzed language ability, speech production measurements, and self-reported outcomes. Overall, the results demonstrate a significant improvement in speech production following speech therapy, especially among younger children.²⁶

Breitenstein et al. (2017) conducted a randomized controlled trial to determine the effect of intensive speech and language therapy in adults with chronic aphasia after stroke. Across rehabilitation centers in Germany, adults younger than 70 years of age with persistent aphasia greater than or equal to 6 months post-stroke were randomized into an intervention or a waiting list group. Participants had at least 10 hours of intensive speech and language therapy for 3 weeks, with a language test as the primary outcome. Overall, the intervention group showed greater improvements in the language test, as well as in linguistic abilities, and improved psychosocial quality of life, compared with the waitlisted group. The authors concluded that 3 weeks of intensive speech and language therapy under routine clinical conditions significantly enhances everyday communication in chronic aphasia. These findings challenge the long-held assumption that language recovery is limited in the chronic stage post-stroke.²⁷

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	04/10/2025	Original Date.
Version 2	04/21/2026	Annual Review. Removed option for non-SLP medical professionals (e.g., registered nurses) to provide SLP services. Updated indications for specific conditions or diagnoses. Added indications for appropriate amount, frequency, and duration of treatment; fluency disorders; evaluation of laryngeal function; swallowing function; and therapeutic services related to cognitive function. Updated Medical Evidence section and added references.



Cohere Medicare Advantage Policy – Application of Skin Substitutes to the Lower Extremities

Clinical Policy for Medical Necessity Review

Version: 1

Cohere Health UMC Approval Date: November 4, 2025

Last Annual Review: Not Applicable

Revision: Not Applicable

Next Annual Review: November 4, 2026

Important Notices

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Policy Information:

Specialty Area: Surgical Wound Care

Policy Name: Cohere Medicare Advantage Policy - Application of Skin Substitutes to the Lower Extremities

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Application of Skin Substitutes to the Lower Extremities

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1,2}

- [Local Coverage Determination \(LCD\). Application of bioengineered skin substitutes to lower extremity chronic non-healing wounds \(L35041\)](#)
 - [Billing and Coding: Application of bioengineered skin substitutes to lower extremity chronic non-healing wounds\(A54117\)](#)

Description

Skin substitutes are advanced wound care therapies designed to replace, supplement, or stimulate skin regeneration when the body's natural healing response is impaired. These products may be derived from human (allogeneic or autogenic), animal (xenogeneic), or synthetic sources, and can be either acellular (structural scaffolds) or cellular (containing viable cells).³ Cellular skin therapies provide skin cells to generate a source of growth factors and nutrients that promote tissue regeneration. Acellular skin therapies are made of collagen or another substrate in which cells can migrate to begin tissue regeneration.⁴ Skin substitutes are primarily used for chronic, non-healing wounds, such as diabetic foot ulcers or venous leg ulcers, that fail to respond to standard care.⁵

Skin substitute application requires wound bed preparation, such as infection control or removal of necrotic tissue.⁶ Once the wound bed is prepared, the skin substitute material is applied directly on the wound and may require additional adhesives or dressings.⁶ The skin substitute may need to be monitored with follow-up applications or dressing changes.⁶

Medical Necessity Criteria

Indications

Application of skin substitutes to the lower extremities is considered appropriate if **ALL** of the following are **TRUE**:

- **ANY** of the following regarding failed response¹:
 - The wound^A has failed to respond to documented appropriate wound-care measures; **OR**
 - The wound has increased in size or depth; **OR**
 - The wound has not changed in baseline size or depth and has no indication that improvement is likely (such as granulation, epithelialization, or progress towards closing); **AND**
- The wound has **ALL** of the following characteristics¹:
 - Partial-thickness skin defect^B or full-thickness skin defect^C involving tendon, muscle, or joint capsule, and not exhibiting exposed bone or sinus tracts, with a clean granular base; **AND**
 - Skin deficit greater than or equal to 1.0 square centimeter (cm) in size; **AND**
 - Clean and free of necrotic debris or exudate; **AND**
 - Control of edema, venous hypertension, or lymphedema; **AND**
 - Control of any nidus of infection or colonization with bacterial or fungal elements; **AND**
 - Elimination of underlying cellulitis, osteomyelitis, foreign body, or malignant process; **AND**
 - Appropriate debridement of necrotic tissue or foreign body (e.g., exposed bone or tendon); **AND**
 - Provision of wound environment to promote healing (e.g., protection from trauma and contaminants, elimination of inciting or aggravating processes); **AND**
 - Arterial perfusion to the wound is adequate, as evidenced by **ANY** of the following:
 - Ankle-brachial index (ABI) greater than or equal to 0.6; **OR**
 - Toe pressure greater than 30 mmHg; **AND**
- The patient has **ANY** of the following specific wound etiologies¹:
 - Partial or full-thickness diabetic foot ulcer (DFU) from trauma or infection, with **ALL** of the following:

- Confirmation of a type I or type II diabetes diagnosis; **AND**
- Documentation of medical management for the diagnosis; **AND**
- Failed response to documented wound-care measures of greater than 4 weeks, during which the patient is compliant with recommendations; **AND**
- Conservative management has included appropriate non-weight-bearing or offloading pressure therapy; **OR**
- Partial or full-thickness venous leg ulcer (VLU) from trauma or infection, with **ALL** of the following:
 - Presence of venous stasis ulcer for greater than or equal to 3 months; **AND**
 - Failed response to appropriate wound care for greater than or equal to 30 days with documented compliance; **AND**
 - Conservative management has included compression therapy with documented diligent use of multilayer dressings, compression stockings of greater than 20 mmHg pressure, or pneumatic compression; **OR**
- The pre-service record documents **ALL** of the following¹:
 - Reasoning for why the wound has failed to respond to standard wound care treatment of greater than 4 weeks; **AND**
 - Specific interventions that have failed; **AND**
 - Updated medical history; **AND**
 - Review of pertinent medical problems that may have occurred since the previous wound evaluation; **AND**
 - Explanation of the planned skin replacement surgery with choice of skin substitute graft product; **AND**
 - Procedure risks and complications have been reviewed and documented; **AND**
 - A comprehensive treatment plan; **AND**
 - Product to be used has FDA clearance/approval or is designated a 361 HCT/P exemption; **AND**
 - **ANY** of the following regarding nicotine cessation:
 - Smoking cessation counseling and cessation measures prescribed; **OR**
 - The patient is a nonsmoker.

Non-Indications

Application of skin substitutes to the lower extremities is not considered appropriate if **ANY** of the following is **TRUE**¹:

- Partial-thickness skin defect with the retention of epithelial appendages; **OR**
- Simultaneous use of more than one product for the episode of wound is not covered (product change within the episode of wound is allowed)
- No more than 10 applications per wound per 12-week period of care; **OR**
- Repeat or alternative applications when a previous full course of applications was unsuccessful²; **OR**
- Retreatment of healed ulcers (i.e., those showing greater than 75% size reduction and smaller than 0.5 square cm); **OR**
- Retreatment within 1 year of any given course of skin substitute treatment for a DFU or VLU; **OR**
- Inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis, or continued tobacco smoking without physician's attempt to affect smoking cessation); **OR**
- The patient has a known hypersensitivity to any component of the specific skin substitute (e.g., allergy to avian, bovine, porcine, equine products); **OR**
- Repeat use of surgical preparation services in conjunction with skin substitute application codes.

Definitions

^AChronic wounds: wounds that do not respond to standard wound treatment for at least a 30-day period during organized comprehensive conservative therapy.¹

^BPartial-thickness skin defect: a wound that involves all of the epidermal layer and parts of the dermal layer. There is no muscle, tendon, or bone exposure, and varying amounts of subcutaneous fat may be visible.^{7,8}

^CFull-thickness skin defect: a wound that involves all epidermal and dermal layers. There is no muscle, tendon, or bone exposure, although subcutaneous fat may be visible.^{7,8}

^DUnsuccessful treatment: increased size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closing) for a period of 4 weeks past the start of therapy.¹

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children
15003	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
15004	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children
15005	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
15040	Harvest of skin for tissue cultured skin autograft, 100 sq cm or less

15050	Pinch graft, single or multiple, to cover small ulcer, tip of digit, or other minimal open area (except on face), up to defect size 2 cm diameter
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area

	greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
C5271	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5272	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
C5273	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5274	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
C5275	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound

	surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5276	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
C5277	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5278	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established," Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

Clinical coverage criteria for the application of skin substitutes to the lower extremities were fully defined and established by NCDs and/or LCDs. Cohere Health did not supplement this policy with any additional criteria or interpretations.

Medical Evidence

A growing body of randomized controlled trials (RCTs) and meta-analyses supports the use of certain skin substitutes in improving healing outcomes for diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) compared with standard care alone.^{9,10} The number of such products has grown substantially over the last 20 years. A 2024 systematic review with meta-analysis concluded that “enough evidence is still lacking to determine a statistical difference between broad categories” of skin substitutes.¹¹ However, application is generally limited to products with robust clinical evidence from well-designed RCTs.

Santema et al. (2016) conducted a meta-analysis of 17 RCTs evaluating the effectiveness of skin substitutes for healing chronic wounds and limb salvage in patients with DFUs. Pooled results showed that standard care plus skin substitutes may increase the chance of complete wound closure versus standard care alone (measured in 13 trials). Pooled results also showed lower amputation rates in patients treated with skin substitutes (only in trials including lower limb amputation incidence).⁹

Chronic venous hypertension is a common contributing factor in non-healing wounds. Venous reflux ultrasonography should be performed before application of a skin substitute for a venous leg ulcer (VLU). Gohel et al. (2018) randomized patients with VLUs to compression therapy with early endovenous ablation of superficial venous reflux or to compression therapy alone, with the possibility of ablation delayed. In patients in the early intervention group, time to ulcer healing was 56 days, compared with 82 days in the compression only with deferred intervention group. This trial found that VLUs heal faster with prompt venous intervention compared with compression therapy alone, and it underscores the importance of early venous duplex ultrasound evaluation and Doppler reflux testing when possible.¹²

Reddy et al. (2008) performed a systematic literature review of RCTs evaluating therapies for pressure ulcers. The authors found no clear evidence that one type of support surface or dressing was more effective than another in improving wound healing. Also, not all wound types have been shown to

respond effectively to the application of skin substitutes. RCTs captured in this review have generally failed to demonstrate a clinically significant benefit of skin substitutes over the standard of care for pressure ulcers. Many meta-analyses and systematic reviews on skin substitutes for chronic wounds exclude or provide insufficient evidence for pressure ulcers.¹³

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Policy Revision History/Information

Original Date: November 4, 2025		
Review History		



Cohere Medical Policy – Application of Skin Substitutes to the Lower Extremities

Clinical Policy for Medical Necessity Review

Version: 1

Cohere Health UMC Approval Date: November 4, 2025

Last Annual Review: Not Applicable

Revision: Not Applicable

Next Annual Review: November 4, 2026

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice.

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Policy Information:

Specialty Area: Surgical Wound Care

Policy Name: Cohere Medical Policy - Application of Skin Substitutes to the Lower Extremities

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Application of Skin Substitutes to the Lower Extremities

Cohere Health takes an evidence-based approach to reviewing procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. procedures should be requested after a clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why procedures were inconclusive, or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Skin substitutes are advanced wound care therapies designed to replace, supplement, or stimulate skin regeneration when the body's natural healing response is impaired. These products may be derived from human (allogeneic or autogenic), animal (xenogeneic), or synthetic sources, and can be either acellular (structural scaffolds) or cellular (containing viable cells).¹ Cellular skin therapies provide skin cells to generate a source of growth factors and nutrients that promote tissue regeneration. Acellular skin therapies are made of collagen or another substrate in which cells can migrate to begin tissue regeneration.² Skin substitutes are primarily used for chronic, non-healing wounds, such as diabetic foot ulcers or venous leg ulcers, that fail to respond to standard care.³

Skin substitute application requires wound bed preparation, such as infection control or removal of necrotic tissue.⁴ Once the wound bed is prepared, the skin substitute material is applied directly on the wound and may require additional adhesives or dressings.⁴ The skin substitute may need to be monitored with follow-up applications or dressing changes.⁴

Medical Necessity Criteria

Indications

Application of skin substitutes to the lower extremities is considered appropriate if **ANY** of the following are **TRUE**:

- **ALL** of the following:
 - The patient is greater than or equal to 18 years of age; **AND**
 - **ANY** of the following regarding nicotine use⁵:
 - The patient is a current nicotine user with no product use for 4 weeks; **OR**
 - The patient has no history of nicotine product use within the last 12 months; **OR**
 - The patient has no lifetime history of nicotine product use; **AND**
 - The wound has **ALL** of the following characteristics⁶:
 - Partial-thickness skin defect^A or full-thickness skin defect^B without exposure of muscle, tendon, or bone; **AND**
 - No current infection; **AND**
 - No necrotic debris; **AND**
 - Failure to reduce by greater than 50% in area compared with baseline; **AND**
 - Arterial perfusion to the wound is adequate, as evidenced by **ANY** of the following⁷:
 - Ankle-brachial index (ABI) between 0.6-1.2; **OR**
 - Toe pressure greater than or equal to 50 mmHg; **OR**
 - Transcutaneous oxygen pressure (TcPO₂) adjacent to the wound of greater than or equal to 30 mmHg; **AND**
 - Failure of conservative management for greater than or equal to 4 weeks, including **ALL** of the following⁸⁻¹⁰:
 - Regular excisional debridement; **AND**
 - Application of wound dressings to control for infection and moisture; **AND**
 - Documentation of wound dimensions at the initial and each subsequent visit; **AND**
 - Utilization of offloading or compression therapy; **AND**
 - Treatment has been provided in an outpatient setting (e.g., provider office, wound center, or ambulatory surgery center); **AND**
 - The patient has **ANY** of the following specific wound etiologies:

- Diabetic foot ulcer (DFU), with **ALL** of the following^{8,9}:
 - Confirmation of a type I or type II diabetes diagnosis; **AND**
 - Recent (within 3 months) hemoglobin A1c (Hgb A1c) of less than 8%; **AND**
 - Ongoing aggressive off-loading is being practiced (e.g., total contact casting, walker boot, knee scooter, orthotic shoe); **AND**
 - The product is **ANY** of the following:
 - Amnioband¹⁰; **OR**
 - Apligraf¹¹; **OR**
 - Dermagraft¹²; **OR**
 - Epifix¹³; **OR**
 - Grafix Core¹⁴; **OR**
 - Grafix Prime¹⁴; **OR**
 - Graftjacket¹⁵; **OR**
 - Integra Dermal Regeneration Template¹⁶; **OR**
 - Integra Flowable Wound Matrix¹⁷; **OR**
 - Oasis Ultra Tri-Layer Matrix¹⁸; **OR**
 - Oasis Wound Matrix¹⁹; **OR**
 - Theraskin²⁰; **OR**
- Venous leg ulcer (VLU), with **ALL** of the following²¹:
 - Venous reflux ultrasonography has been performed and is pertinent to the current presentation, and **ANY** of the following:
 - No significant reflux is seen; **OR**
 - Refluxing veins contributing to non-healing have been treated appropriately²²; **AND**
 - The patient has no contributory arterial disease; **AND**
 - The highest tolerated compression therapy is being utilized; **AND**
 - The product is **ANY** of the following:
 - Amnioband²³; **OR**
 - Apligraf²⁴; **OR**
 - Dermagraft²⁵; **OR**
 - Epifix²⁶; **OR**
 - Oasis Wound Matrix²⁷; **OR**
 - Theraskin²⁸; **AND**
- The plan of care (POC) documents **ALL** of the following^{9,21}:
 - The product is being applied to a clean tissue bed free of exudate or necrosis; **AND**

- The product is being applied in an outpatient treatment setting (e.g., provider office, wound center, or ambulatory surgery center); **AND**
- No more than 10 applications are being performed within a 12-week period; **AND**
- Documentation supports an ongoing benefit to wound healing with each application beyond the fifth application.

Non-Indications

Application of skin substitutes to the lower extremities is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has a history of hypersensitivity reaction to the product or its components; **OR**
- The application is a repeat or alternative application within 1 year of initial skin substitute treatment failure²⁹; **OR**
- The application is for a pressure wound³⁰; **OR**
- The patient is actively enrolled in hospice or has an end-stage disease under palliative care; **OR**
- The application is to a wound known to have a malignancy; **OR**
- The patient has an active Charcot deformity⁹; **OR**
- The application is being performed for cosmetic or experimental use; **OR**
- The application is being performed in the patient's home setting.

Definitions

^APartial-thickness skin defect: a wound that involves all of the epidermal layer and parts of the dermal layer. There is no muscle, tendon, or bone exposure, and varying amounts of subcutaneous fat may be visible.^{31,32}

^BFull-thickness skin defect: a wound that involves all epidermal and dermal layers. There is no muscle, tendon, or bone exposure, although subcutaneous fat may be visible.^{31,32}

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

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15040	Harvest of skin for tissue cultured skin autograft, 100 sq cm or less

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Q4101	Apligraf, per square centimeter
Q4102	Oasis Wound Matrix, per square centimeter
Q4105	Integra Dermal Regeneration Template (DRT) or Integra Omnigraft Dermal Regeneration Matrix, per square centimeter
Q4106	Dermagraft, per square centimeter
Q4107	GraftJacket Regenerative Tissue Matrix-Ulcer Repair, per square centimeter
Q4114	Integra Flowable Wound Matrix, injectable, 1 cc
Q4121	TheraSkin, per square centimeter

Q4124	Oasis Ultra Tri-Layer Wound Matrix, per square centimeter
Q4132	Grafix CORE and GrafixPL CORE, per square centimeter
Q4133	Grafix prime, GrafixPL prime, Stravix and StravixPL, per square centimeter
Q4151	AmnioBand or Guardian, per square centimeter
Q4168	AmnioBand, 1 mg
Q4186	EpiFix, per square centimeter

Medical Evidence

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Reddy et al. (2008) performed a systematic literature review of RCTs evaluating therapies for pressure ulcers. The authors found no clear evidence that one type of support surface or dressing was more effective than another in improving wound healing. Also, not all wound types have been shown to

respond effectively to the application of skin substitutes. RCTs captured in this review have generally failed to demonstrate a clinically significant benefit of skin substitutes over the standard of care for pressure ulcers. Many meta-analyses and systematic reviews on skin substitutes for chronic wounds exclude or provide insufficient evidence for pressure ulcers.³⁰

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Policy Revision History/Information

Original Date: November 4, 2025		
Review History		

Cohere Medicare Advantage Policy – Home Respiratory Care

Clinical Policy for Medical Necessity Review

CHP-076-2 Version 2

Cohere UMC Approval Date: April 9, 2026

Last Annual Review: April 9, 2026

Revision Date: Not applicable

Next Annual Review: April 9, 2027

Specialty: Home Health

Population Type: Adult (18+ years old), Pediatric (0-17 years old)

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Procedure Codes (CPT/HCPCS)

Service: Home Respiratory Care	
Code	Description
99503	Home visit for respiratory therapy care (eg, bronchodilator, oxygen therapy, respiratory assessment, apnea evaluation)
99504	Home visit for mechanical ventilation care

Important Notices

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Service: Home Respiratory Care - Description

Home health care is a form of caregiving for a patient who is medically complex enough to require substantial nursing or medical support services in the home. Home respiratory care includes respiratory therapy, such as the administration of bronchodilators, oxygen therapy, mechanical ventilation, or other therapeutic interventions from infancy to adulthood. It may also encompass home mechanical ventilation, provided that the patient is unstable on a ventilator, requires frequent adjustments, or has been recently discharged from an inpatient stay. Home respiratory care allows patients to reside in a familiar environment and avoid costly hospitalization or institutional care while also receiving effective, adequate medical treatment.²⁻¹³

Service: Home Respiratory Care - Medical Necessity Criteria

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to *Cohere Medicare Advantage Policy - Home Respiratory Care* is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 - Related CMS Policies (NCDs or LCDs)¹

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	No NCD available	N/A	N/A	N/A
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use Cohere Medicare Advantage internal coverage criteria

Indications

- **Home respiratory care** is considered appropriate if **ALL** of the following are **TRUE**:
 - **ANY** of the following^{14,15}:
 - Leaving the home requires the help of another person or medical equipment such as crutches, a walker, or a wheelchair; **OR**
 - Receiving medical services outside the home poses substantial medical risk; **AND**
 - It is difficult for the patient to leave the home and they typically cannot do so (e.g., the patient is considered homebound)^A; **AND**
 - After initiation of home healthcare, a physician evaluates and recertifies the plan of care (POC) every 30 days, including **ALL** of the following^{7,16}:
 - Short- and long-term goals with documentation on how goals will be attained; **AND**
 - An estimated time of when goals will be attained; **AND**
 - Measurable goals; **AND**

- The number of visits requested is appropriate for the diagnosis; **AND**
- Home respiratory care is ordered and directed by an attending physician or a health care provider practicing within the scope of their license as part of a written POC¹⁵; **AND**
- The service is inherently complex such that it can only be safely and effectively performed by a qualified technical or professional health personnel such as a registered nurse, a licensed practical (vocational) nurse, a respiratory therapist, or other skilled staff.

Non-Indications

- **Home respiratory care** is not considered appropriate if **ANY** of the following is **TRUE**:
 - The treatment plan does not demonstrate a continued need for skilled respiratory care¹⁷; **OR**
 - Services are custodial in nature (i.e., nonmedical services to assist with daily living and independence); **OR**
 - Services are solely requested for the comfort or convenience of the caregiver or family member.

Definitions and Notes

^AEven if a patient is homebound, they can still leave the home for medical treatment, religious services, or to attend an adult day care center without putting their homebound status at risk. Leaving home for short periods of time, or for special non-medical events such as a family reunion, funeral, or graduation, should also not affect homebound status. The patient may also take occasional trips to the barber or beauty parlor.¹⁴

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.¹

The potential clinical harms of using these criteria for home respiratory care may include:

- Adverse effects from delayed or denied treatment.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria for home respiratory care may include:

- Improved patient selection for home respiratory care, resulting in better long-term outcomes.
- Maintenance of rigorous patient safety standards aligned to best available evidence.
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.

Medical Evidence

Home respiratory therapy plays an important role in the outpatient management of medically complex infants and children. Respiratory conditions of prematurity, for example, are commonly treated with home therapy. Bronchopulmonary dysplasia (BPD), a chronic lung disease that occurs among infants who have received extended mechanical ventilation, may be treated in the home with supplemental oxygen or other respiratory therapy. In some scenarios, the child may only be safely discharged from the inpatient setting when home respiratory care is established. Children with severe respiratory disease may be at higher risk for community-acquired illness, particularly when they have not reached the appropriate age of vaccination for common communicable diseases. In these cases, outpatient care may confer too high of a medical risk, necessitating in-home care to ensure patient safety.³

The Lancet published international guidelines and eligibility criteria for home oxygen therapy in 2023. The authors noted that home oxygen is a valuable treatment for acute and chronic conditions that may improve survival, restore functional capacity, and ameliorate dyspnea among appropriately selected patients. They reviewed 30 published guidelines for continuous oxygen therapy and found eligibility and minimum hypoxemia thresholds to be highly variable. They reviewed the eligibility criteria for home oxygen use of 193 United Nations countries and found only 46 provided criteria for publicly funded continuous home oxygen therapy, 34 had guidance for ambulatory oxygen therapy, and 23 had criteria for nocturnal oxygen therapy.²

In 2020, the American Thoracic Society issued guidelines detailing the home use of oxygen therapy for adult patients with chronic lung disease. Strong recommendations were made regarding long-term oxygen therapy, at least 15 hours a day for the duration of the individual's life, among patients with severe chronic obstructive pulmonary disease (COPD) and severe interstitial lung disease (ILD) with severe chronic resting room air hypoxemia. The authors also endorsed the importance of patient and caregiver education regarding safe oxygen use in the home setting, including fire prevention, smoking cessation, and tripping hazards.⁷

In 2019, the American Thoracic Society published guidelines for home oxygen therapy in children with chronic lung and pulmonary vascular diseases. The task force consisted of specialists from a variety of fields, including pediatric and neonatal specialists, respiratory therapy specialists, nursing specialists, population health specialists, and parents. The panel made strong recommendations for the use of home oxygen therapy in children with cystic fibrosis, bronchopulmonary dysplasia, pulmonary hypertension without congenital heart disease, or interstitial lung disease as long as the respiratory condition was also complicated by chronic hypoxemia. The panel also strongly recommended that patients with pulmonary hypertension with congenital heart disease complicated by chronic hypoxemia should not be treated with home oxygen therapy until consulted by a pediatric pulmonologist or cardiologist. The authors noted the lack of empirical evidence regarding implementation, monitoring, and discontinuation of home oxygen therapy, and highlighted the need for future research in home oxygen therapy in children.⁸

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	04/10/2025	Original Date.
Version 2	04/09/2026	Annual review. No changes to procedure codes. Updated description. Clarified language to improve usability and organization. Updated plan of care indication. Moved homebound note to Definitions and Notes section. Updated Harms and Benefits section. Expanded Medical Evidence section. Updated references.



Cohere Medicare Advantage Policy – Home Respiratory Care

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: April 10, 2025

Important Notices

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Guideline Information:

Specialty Area: Home Health

Guideline Name: Cohere Medicare Advantage Policy - Home Respiratory Therapy

Date of last literature review: 4/9/2025

Document last updated: 4/9/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Home Respiratory Care

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.

- There are no applicable NCDs and/or LCDs for home respiratory care.

Recommended Clinical Approach

Home health care is a form of caregiving for a patient who is medically complex enough to require substantial nursing or medical support services in the home. In general, the individual must be unable to obtain care from a facility outside of the home due to an unacceptable level of medical risk, considerable relative effort (e.g., the individual is considered “homebound”), or the fact that the service is more appropriately delivered in a home setting. Home respiratory care includes respiratory therapy, such as the administration of bronchodilators, oxygen therapy, or other therapeutic interventions. It may also encompass home mechanical ventilation, provided that the patient is unstable on a ventilator, requires frequent adjustments, or has been recently discharged from an inpatient stay. Home respiratory care is beneficial because it allows patients to reside in a familiar environment and avoid costly hospitalization or institutional care while also receiving effective, adequate medical treatment.¹⁻⁵

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of home respiratory therapy. This process

helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Reduced supervision. In the home setting, inappropriately selected patients who are medically unstable and would benefit more from inpatient care may be inadequately monitored, conferring a potential risk for clinical decompensation or incomplete care. This highlights the importance of careful patient selection for those who require some level of skilled home care but are stable enough not to require formalized inpatient treatment.⁵
- Dependence on family member or caregiver. As home health is limited in nature and requires participation from caregivers (often family members) to be successful, the patient must rely on their caregiver to be educated and trained in providing their care. This may result in relationship challenges between patient and caregiver.^{1-3,5}
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Reduced risk of nosocomial infection. Receiving care in the home setting inherently removes the risk of nosocomial infections, including line-associated sepsis, hospital-acquired pneumonia, or viral infections.⁵
- Safe, familiar, comfortable environment. Home care allows skilled services to be conducted in an environment that is already familiar to the patient, potentially improving patient participation in care and reducing overall stress levels – particularly among children.²⁻⁵
- Reduced risk of long-term institutionalization. With the intermittent involvement of skilled professionals in the home setting, primary caregivers may be less likely to institutionalize the patient as they receive tangible support from home health professionals.^{5,10}
- Less expensive and burdensome to family and caregivers. As compared to traditional inpatient or outpatient care, home care is generally more affordable and less burdensome to the family, allowing the patient to

receive skilled care without requiring transportation beyond the home. This also reduces barriers to accessing care.²⁻⁵

- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Home respiratory care** is considered appropriate if **ALL** of the following are **TRUE**^{1-3,6,7,23,24}:

◆ **ANY** of the following:

- In order to leave the home, the patient requires the help of another person or medical equipment such as crutches, a walker, or a wheelchair; **OR**
- Receiving medical services outside the home would expose the patient to substantial medical risk; **AND**

◆ It is difficult for the patient to leave the home and they typically cannot do so (e.g., the patient is considered homebound)*; **AND**

◆ After the patient begins receiving home healthcare, a physician evaluates and recertifies the plan of care (POC) every 60 days, including **ALL** of the following²²:

- Short- and long-term goals with documentation on how goals will be obtained; **AND**
- An estimated time of when goals will be attained; **AND**
- Measurable objectives; **AND**
- The number of visits requested is appropriate for the diagnosis; **AND**

◆ Home respiratory care is ordered and directed by an attending

physician or a health care provider practicing within the scope of their license as part of a written plan of care; **AND**

- ◆ The service is inherently complex such that it can only be safely and effectively performed by a qualified technical or professional health personnel such as a registered nurse, a licensed practical (vocational) nurse, a respiratory therapist, or other skilled staff.

*NOTE: Even if a patient is homebound, they can still leave the home for medical treatment, religious services, or to attend an adult day care center without putting their homebound status at risk. Leaving home for short periods of time or for special non-medical events, such as a family reunion, funeral, or graduation, should also not affect homebound status. The patient may also take occasional trips to the barber or beauty parlor.

Non-Indications

→ **Home respiratory care** is not considered appropriate if **ANY** of the following is **TRUE**^{1-3,6,7}:

- ◆ The treatment plan does not demonstrate a continued need for skilled respiratory care; **OR**
- ◆ Services are custodial in nature (i.e., nonmedical services to assist with daily living and independence); **OR**
- ◆ Services are solely requested for the comfort or convenience of the caregiver or family member versus the medical necessity of the patient.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
99503	Home visit for respiratory therapy care (eg, bronchodilator, oxygen therapy, respiratory assessment, apnea evaluation)
99504	Home visit for mechanical ventilation care

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Home respiratory therapy plays an important role in the outpatient management of medically complex infants and children. Respiratory conditions of prematurity, for example, are commonly treated with home therapy. Bronchopulmonary dysplasia (BPD), a chronic lung disease that occurs among infants who have received extended mechanical ventilation, may be treated in the home with supplemental oxygen or other respiratory therapy. In some scenarios, the child may only be safely discharged from the inpatient setting when home respiratory care is established. Children with severe respiratory disease may be at higher risk for community-acquired illness, particularly when they have not reached the appropriate age of vaccination for common communicable diseases. In these cases, outpatient care may confer too high of a medical risk, necessitating in-home care to ensure patient safety.^{2,3}

In 2020, the American Thoracic Society issued guidelines detailing the home use of oxygen therapy for adult patients with chronic lung disease. Strong recommendations were made regarding long-term oxygen therapy, at least 15 hours a day for the duration of the individual's life, among patients with severe chronic obstructive pulmonary disease (COPD) and severe interstitial lung disease (ILD) with severe chronic resting room air hypoxemia. The authors also endorsed the importance of patient and caregiver education regarding safe oxygen use in the home setting, including fire prevention, smoking cessation, and tripping hazards.⁷

The Lancet published international guidelines and eligibility criteria for home oxygen therapy in 2023. The authors note that home oxygen is a valuable treatment for acute and chronic conditions that may improve survival, restore functional capacity, and ameliorate dyspnea among appropriately selected patients. They reviewed 30 published guidelines for continuous oxygen therapy and found eligibility and minimum hypoxemia thresholds to be highly variable. They reviewed the eligibility criteria for home oxygen use of 193 United Nations countries and found only 46 provided criteria for publicly funded continuous home oxygen therapy, 34 had guidance for ambulatory oxygen therapy, and 23 had criteria for nocturnal oxygen therapy.¹

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Clinical Guideline Revision History/Information

Original Date: April 10, 2025		
Review History		



Cohere Medical Policy – Home Respiratory Care

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: April 10, 2025

Important Notices

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Guideline Information:

Specialty Area: Home Health

Guideline Name: Cohere Medical Policy – Home Respiratory Care

Date of last literature review: 4/9/2025

Document last updated: 4/9/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Home Respiratory Care

Recommended Clinical Approach

Home health care is a form of caregiving for a patient who is medically complex enough to require substantial nursing or medical support services in the home. In general, the individual must be unable to obtain care from a facility outside of the home due to an unacceptable level of medical risk, considerable relative effort (e.g., the individual is considered “homebound”), or the fact that the service is more appropriately delivered in a home setting. Home respiratory care includes respiratory therapy, such as the administration of bronchodilators, oxygen therapy, or other therapeutic interventions. It may also encompass home mechanical ventilation, provided that the patient is unstable on a ventilator, requires frequent adjustments, or has been recently discharged from an inpatient stay. Home respiratory care is beneficial because it allows patients to reside in a familiar environment and avoid costly hospitalization or institutional care while also receiving effective, adequate medical treatment.¹⁻⁵

Medical Necessity Criteria

Indications

→ **Home respiratory care** is considered appropriate if **ALL** of the following are **TRUE**^{1-3,6,7,23,24}:

◆ **ANY** of the following:

- In order to leave the home, the patient requires the help of another person or medical equipment such as crutches, a walker, or a wheelchair; **OR**
- Receiving medical services outside the home would expose the patient to substantial medical risk; **AND**

◆ It is difficult for the patient to leave the home and they typically cannot do so (e.g., the patient is considered homebound)*; **AND**

◆ After the patient begins receiving home healthcare, a physician evaluates and recertifies the plan of care (POC) every 60 days, including **ALL** of the following²²:

- Short- and long-term goals with documentation on how goals will be obtained; **AND**
- An estimated time of when goals will be attained; **AND**
- Measurable objectives; **AND**
- The number of visits requested is appropriate for the diagnosis; **AND**
- ◆ Home respiratory care is ordered and directed by an attending physician or a health care provider practicing within the scope of their license as part of a written plan of care; **AND**
- ◆ The service is inherently complex such that it can only be safely and effectively performed by a qualified technical or professional health personnel such as a registered nurse, a licensed practical (vocational) nurse, a respiratory therapist, or other skilled staff.

*NOTE: Even if a patient is homebound, they can still leave the home for medical treatment, religious services, or to attend an adult day care center without putting their homebound status at risk. Leaving home for short periods of time or for special non-medical events, such as a family reunion, funeral, or graduation, should also not affect homebound status. The patient may also take occasional trips to the barber or beauty parlor.

Non-Indications

→ **Home respiratory care** is not considered appropriate if **ANY** of the following is **TRUE**^{1-3,6,7}:

- ◆ The treatment plan does not demonstrate a continued need for skilled respiratory care; **OR**
- ◆ Services are custodial in nature (i.e., nonmedical services to assist with daily living and independence); **OR**
- ◆ Services are solely requested for the comfort or convenience of the caregiver or family member versus the medical necessity of the patient.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
99503	Home visit for respiratory therapy care (eg, bronchodilator, oxygen therapy, respiratory

	assessment, apnea evaluation)
99504	Home visit for mechanical ventilation care

Medical Evidence

Home respiratory therapy plays an important role in the outpatient management of medically complex infants and children. Respiratory conditions of prematurity, for example, are commonly treated with home therapy. Bronchopulmonary dysplasia (BPD), a chronic lung disease that occurs among infants who have received extended mechanical ventilation, may be treated in the home with supplemental oxygen or other respiratory therapy. In some scenarios, the child may only be safely discharged from the inpatient setting when home respiratory care is established. Children with severe respiratory disease may be at higher risk for community-acquired illness, particularly when they have not reached the appropriate age of vaccination for common communicable diseases. In these cases, outpatient care may confer too high of a medical risk, necessitating in-home care to ensure patient safety.^{2,3}

In 2020, the American Thoracic Society issued guidelines detailing the home use of oxygen therapy for adult patients with chronic lung disease. Strong recommendations were made regarding long-term oxygen therapy, at least 15 hours a day for the duration of the individual's life, among patients with severe chronic obstructive pulmonary disease (COPD) and severe interstitial lung disease (ILD) with severe chronic resting room air hypoxemia. The authors also endorsed the importance of patient and caregiver education regarding safe oxygen use in the home setting, including fire prevention, smoking cessation, and tripping hazards.⁴

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Clinical Guideline Revision History/Information

Original Date: April 10, 2025		
Review History		



Cohere Medicare Advantage Policy – Home Physical and Occupational Therapy (PT/OT)

Clinical Policy for Medical Necessity Review

Version: 2

Policy Number: CHP-075-2

Cohere Health UMC Approval Date: April 9, 2026

Last Annual Review: April 9, 2026

Revision: Not Applicable

Next Annual Review: April 9, 2027

Important Notices

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Policy Information:

Specialty Area: Home Health

Policy Name: Cohere Medicare Advantage Policy - Home Physical and Occupational Therapy (PT/OT)

Policy Number: CHP-075-2

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Home Physical and Occupational Therapy (PT/OT)

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD, NCD, or manual is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs, LCDs, and manuals related to *Cohere Medicare Advantage Policy - Home Physical and Occupational Therapy (PT/OT)* is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the Medicare Benefit Policy Manual.

Table 1 – Related CMS Policies (NCDs or LCDs)²⁻⁶

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy:
LCD	Physical Therapy - Home Health	L33942	Not Fully Established	Services beyond home PT.
LCD	Home Health Occupational Therapy	L34560	Not Fully Established	Services beyond home OT.
LCD	Home Health Physical Therapy	L34564	Not Fully Established	Services beyond home PT.
LCD	Home Health – Psychiatric Care	L34561	Not Fully Established	Services beyond OT in a psychiatric care setting.
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use Medicare Benefit Policy Manual chapter 7.
Internet Only Manual	Medicare Benefit Policy Manual Chapter 7 Home Health Services	Chapter 7 – Section 30.1.1, 30.2, 40.2.1, 40.2.2, 40.2.4	Fully Established	NOTE: Cohere applies the Medicare benefit policy manual chapter 7 to all jurisdictions; therefore, Cohere did not add Medicare Advantage internal coverage criteria to this policy.

Description

Broadly, physical therapy (PT) is the diagnosis and management of movement deficits or disorders through examination, evaluation, referral, consultation, and intervention. This can include restoring, maintaining, or promoting bodily function and purposeful action appropriate to the patient's age and development.^{7,8} PT consists of a prescribed program to relieve symptoms, improve function, and prevent decline or disability. Occupational therapy (OT) involves evaluation, diagnosis, treatment planning, and interventions to support developing, recovering, or maintaining the skills required for age-appropriate self-care, work, education, and community participation.⁹ OT interventions include task-specific training, education, environmental modifications, and adaptive technologies.

For patients with complex medical needs, services such as PT or OT may be best conducted in a home setting. These services help patients regain function and independence, complete household tasks, and engage in personal care. Home health may be recommended as a midpoint level of care between independent living and inpatient hospitalization.

Definitions and Notes

S codes are not payable by Medicare.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
G0157	Services performed by a qualified physical therapist assistant in the home health or hospice setting, each 15 minutes
G0158	Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes
G0159	Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes
G0160	Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes
G0152	Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes
S9129	Occupational therapy, in the home, per diem
S9131	Physical therapy; in the home, per diem

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Policy Revision History/Information

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Review History		
Version 1.1	10/21/2025	CMS update of L33942, effective 08/07/2025- (CMS annual review, no changes to coverage). Updated LCD link and reference. Updated links for Billing and Coding Articles (A57311, A53057) related to update for 10/01/2025. Updated template to current version.
Version 2	04/09/2026	Annual review. Updated template, including addition of "Table 1 - Related CMS Policies" that describes Cohere definition of which LCDs, NCDs, or manuals are not fully established. Removed Cohere Medicare Advantage internal coverage criteria due to the availability of fully established CMS documents per Table 1.

Cohere Medicare Advantage Policy – Home Physical and Occupational Therapy (PT/OT)

Clinical Policy for Medical Necessity Review

CHP-075-2 Version 2

Cohere UMC Approval Date: April 9, 2026

Last Annual Review: April 9, 2026

Revision Date: Not applicable

Next Annual Review: April 9, 2027

Specialty: Home Health

Population Type: Adult (18+ years old), Pediatric (0-17 years old)

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Procedure Codes (CPT/HCPCS)

Service: Home Physical and Occupational Therapy (PT/OT)	
Code	Description
G0152	Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes
G0157	Services performed by a qualified physical therapist assistant in the home health or hospice setting, each 15 minutes
G0158	Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes
G0159	Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes
G0160	Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes
S9129	Occupational therapy, in the home, per diem
S9131	Physical therapy; in the home, per diem

Important Notices

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Service: Home Physical and Occupational Therapy (PT/OT) - Description

Broadly, physical therapy (PT) is the diagnosis and management of movement deficits or disorders through examination, evaluation, referral, consultation, and intervention. This can include restoring, maintaining, or promoting bodily function and purposeful action appropriate to the patient's age and development.^{7,8} PT consists of a prescribed program to relieve symptoms, improve function, and prevent decline or disability. Occupational therapy (OT) involves evaluation, diagnosis, treatment planning, and interventions to support developing, recovering, or maintaining the skills required for age-appropriate self-care, work, education, and community participation.⁹ OT interventions include task-specific training, education, environmental modifications, and adaptive technologies.

For patients with complex medical needs, services such as PT or OT may be best conducted in a home setting. These services help patients regain function and independence, complete household tasks, and engage in personal care. Home health may be recommended as a midpoint level of care between independent living and inpatient hospitalization.

Service: Home Physical and Occupational Therapy (PT/OT) - Medical Necessity Criteria

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria as follows¹:

- Fully established: Applicable LCD, NCD, or manual is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs, LCDs, and manuals related to *Cohere Medicare Advantage Policy - Home Physical and Occupational Therapy (PT/OT)* is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the Medicare Benefit Policy Manual.

Table 1 - Related CMS Policies (NCDs or LCDs)²⁻⁶

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy:
LCD	Physical Therapy - Home Health	L33942	Not Fully Established	Services beyond home PT.
LCD	Home Health Occupational Therapy	L34560	Not Fully Established	Services beyond home OT.
LCD	Home Health Physical Therapy	L34564	Not Fully Established	Services beyond home PT.
LCD	Home Health - Psychiatric Care	L34561	Not Fully Established	Services beyond OT in a psychiatric care setting.
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use Medicare Benefit Policy Manual chapter 7.

Internet Only Manual	Medicare Benefit Policy Manual Chapter 7 Home Health Services	Chapter 7 - Section 30.1.1, 30.2, 40.2.1, 40.2.2, 40.2.4	Fully Established	NOTE: Cohere applies the Medicare benefit policy manual chapter 7 to all jurisdictions; therefore, Cohere did not add Medicare Advantage internal coverage criteria to this policy.

Definitions and Notes

S codes are not payable by Medicare.

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4. Centers for Medicare & Medicaid Services (CMS). Local coverage determination (LCD). Home health physical therapy (L34564). Revision Effective Date May 23, 2024. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34564&ver=83&>
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6. Centers for Medicare & Medicaid Services (CMS). Medicare benefit policy manual: Home health services (Chapter 7, Sections §30.1.1, 30.2, 40.2.1, 40.2.2, and 40.2.4). Revised December 21, 2023. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c07.pdf>
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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	04/10/2025	Original Date.
Version 1.1	10/21/2025	CMS update of L33942, effective 08/07/2025- (CMS annual review, no changes to coverage). Updated LCD link and reference. Updated links for Billing and Coding Articles (A57311, A53057) related to update for 10/01/2025. Updated template to current version.
Version 2	04/09/2026	Annual review. Updated template, including addition of "Table 1 - Related CMS Policies" that describes Cohere definition of which LCDs, NCDs, or manuals are not fully established. Removed Cohere Medicare Advantage internal coverage criteria due to the availability of fully established CMS documents per Table 1.



Cohere Medicare Advantage Policy – Home Physical and Occupational Therapy (PT/OT)

Clinical Policy for Medical Necessity Review

Version: 1.1

Cohere Health UMC Approval Date: April 10, 2025

Last Annual Review: Not Applicable

Revision: October 21, 2025

Next Annual Review: April 10, 2026

Important Notices

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Policy Information:

Specialty Area: Home Health

Policy Name: Home Physical and Occupational Therapy (PT/OT)

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Home Physical and Occupational Therapy (PT/OT)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1-2, 23-24}

- [Local Coverage Determination \(LCD\). Physical therapy – Home health \(L33942\)](#)
 - [Billing and Coding: Physical therapy – Home Health \(A57311\)](#)
- [Local Coverage Determination \(LCD\). Home health occupational therapy \(L34560\)](#)
 - [Billing and Coding: Home health occupational therapy \(A53057\)](#)

Description

For patients with complex medical needs, services such as physical therapy or occupational therapy may be best conducted in a home setting. Home physical therapy and occupational therapy, for example, may treat people with developmental or congenital disabilities, those with chronic conditions, or those in rehabilitation and recovery from an injury or illness. These services help patients regain function and independence, complete household tasks, and engage in personal care. Home health may be recommended as a midpoint level of care between independent living and inpatient hospitalization. It may also facilitate access to care for rural patients or those who would be safer at home than attempting transport to an outpatient facility. Home health is utilized across the age continuum, from medically complex babies to adults of advanced age. Home health is cost-effective, convenient, and effective among appropriately selected patients.¹⁻⁹

Medical Necessity Criteria

Indications

Home health physical therapy or occupational therapy services are considered appropriate if **ALL** of the following are **TRUE**:

- **ANY** of the following^{3-4,7-8}:
 - In order to leave the home, the patient requires the help of another person or medical equipment such as crutches, a walker, or a wheelchair; **OR**
 - Receiving medical services outside the home would expose the patient to substantial medical risk; **AND**
- It is difficult for the patient to leave the home, and they typically cannot do so (e.g., the patient is considered homebound)*; **AND**
- Therapy services are provided or supervised by a qualified physical or occupational therapist, and the service was referred to by the patient's physician^{1-2,9}; **AND**
- After the patient begins receiving home healthcare, a physician evaluates and recertifies the plan of care (POC) every 60 days, including **ALL** of the following¹⁷⁻¹⁸:
 - Short- and long-term goals with documentation on how goals will be obtained; **AND**
 - An estimated time of when goals are expected to be attained; **AND**
 - Measurable objectives; **AND**
 - The number of visits requested is appropriate for the diagnosis; **AND**
 - Therapy interventions to be used; **AND**
- **ANY** of the following is **TRUE**:
 - The service is for physical therapy, and **ALL** of the following:
 - The POC addresses specific therapeutic goals and documents the patient's functional limitations in terms that are objective and measurable¹; **AND**
 - The POC addresses the condition for which physical therapy is an accepted method of treatment (may be a functional diagnosis, not necessarily a clinical diagnosis, as defined by standards of medical practice), with the expectation that the condition will improve significantly in a reasonable period of time¹; **AND**

- Reasonable and necessary to the treatment of the illness or injury, or to the restoration or maintenance of function affected by the illness or injury¹; **AND**
- The service addresses objective measurements of balance, strength, coordination, or mobility as well as functional limitations of the patient's condition¹; **AND**
- Treatment notes should be completed per visit. They should be legible and clearly relate back to the established goals. Symbols, acronyms, and notation used in treatment notes should be consistent with standard documentation and discernible, either on their face or by supplied legends¹; **AND**
- The functional progress should be assessed at the end of the prescribed number of visits; if no progress, the reason for lack of progress and/or alternative treatment strategy should be documented¹; **OR**
- The service is for occupational therapy, and **ALL** of the following:
 - The service is contingent upon the patient's need for occupational therapy, whether the goal includes maintenance or improvement²; **AND**
 - The POC addresses specific therapeutic goals and documents the patient's functional limitations in terms that are objective and measurable²; **AND**
 - The POC addresses the diagnosis(es), treatment goals, duration, and frequency of services²; **AND**
 - The service is **ANY** of the following²:
 - The service is an initial evaluation, and **ALL** of the following:
 - The patient has a new diagnosis or the condition is being treated in a new setting (e.g., from inpatient to home); **AND**
 - Objective measurements of activities of daily living ([ADLs] e.g., eating, swallowing, bathing, dressing, toileting, walking, climbing stairs); **AND**
 - Evaluations of clinical findings (e.g., chronicity/severity of the problem, the possibility of multi-system involvement or pre-existing conditions); **AND**
 - The extent and duration of loss of function, prior functional level, social/environmental considerations, educational level, the patient's overall physical and cognitive health status,

social/cultural supports, psychosocial factors, or use of adaptive equipment; **OR**

- The service is a continued treatment²; **OR**
- The service is maintenance therapy to maintain the patient's current condition or prevent or slow further deterioration, even if no improvement is expected²; **OR**
- The service is a re-evaluation, and **ALL** of the following²:
 - The professional assessment indicates progress toward current goals, a significant decline in the patient's condition or functional status that was not anticipated in the POC, or establishes interventions for newly developed impairments; **AND**
 - The professional assessment indicates whether continuing care, modifying goals and/or treatment, or terminating services is appropriate; **AND**
 - The service is re-evaluated at least once every 30 days for each therapy discipline; **OR**
- The treatment approach includes **ANY** of the following²:
 - Basic activities of daily living (BADLs) training; **OR**
 - Instrumental activities of daily living (IADLs) training; **OR**
 - Muscle testing, manual; **OR**
 - Range of motion (ROM) measurements; **OR**
 - Standardized cognitive performance testing (e.g., Ross Information Processing Assessment, Loewenstein Occupational Therapy Cognitive Assessment [LOTCA], Motor-Free Visual Perception Test [MVPT], Allen Cognitive Test [ACL]); **OR**
 - Therapeutic exercise; **OR**
 - Muscle re-education; **OR**
 - Neuromuscular re-education; **OR**
 - Cognitive training; **OR**
 - Perceptual motor training; **OR**
 - Fine motor coordination/strengthening/ coordination; **OR**
 - Orthotics fitting/training (splinting, casting, strapping); **OR**
 - Adaptive equipment fabrication and training; **OR**
 - Environment modification, recommendations/training; **OR**
 - Patient/caregiver education/training; **OR**
 - Transfer training; **OR**

- Functional mobility training; **OR**
- Manual therapy; **OR**
- Massage therapy; **OR**
- Ultrasound; **OR**
- Physical agent modalities; **OR**
- Neurodevelopment training; **OR**
- Rehabilitation services for vision impairment or blindness; **OR**
- Biofeedback training; **OR**
- Oral or pharyngeal swallowing function evaluation**; **OR**
- Swallowing dysfunction and/or oral function for feeding treatment.

*NOTE: Even if a patient is homebound, they can still leave the home for medical treatment, religious services, or to attend an adult day care center without putting their homebound status at risk. Leaving home for short periods of time or for special non-medical events, such as a family reunion, funeral, or graduation, should also not affect homebound status. The patient may also take occasional trips to the barber or beauty parlor.

**NOTE: The evaluation of oropharyngeal swallowing dysfunction may include: history of patient's disorder and awareness of swallowing disorder, and indications of localization and nature of disorder; medical status including nutritional and respiratory status; oral anatomy/physiology (labial control, lingual control, palatal function); pharyngeal function; laryngeal function; ability to follow directions, alertness; efforts and interventions used to facilitate normal swallow (compensatory strategies such as chin tuck, dietary changes, etc.); or identifying symptoms during attempts to swallow. The clinical examination can be divided into 2 phases: the preparatory examination with no swallow; the initial swallow examination with actual swallow while physiology is observed. Based on the findings, an instrumental exam may be recommended.

Non-Indications

Home health physical therapy or occupational therapy services are not considered appropriate if **ANY** of the following is **TRUE**:

- Services are custodial in nature (i.e., nonmedical services to assist with daily living and independence)⁵; **OR**
- Services are solely requested for the comfort or convenience of the caregiver or family member versus the medical necessity of the patient¹⁹; **OR**
- The patient suffered a temporary loss or reduction of function and could reasonably be expected to improve over time without the services of the therapist¹⁻²; **OR**
- Therapy that duplicates services that are provided concurrently by any other type of therapy, such as speech and language therapy, should provide different treatment goals, plans, and therapeutic modalities¹⁻²; **OR**
- The service is for physical therapy, and **ANY** of the following¹:
 - The service is provided routinely to identify if the patient might need or benefit from physical therapy; **OR**
 - The service is related to activities for the general physical welfare of the patient (e.g., to promote overall fitness); **OR**
 - Treatment for incontinence, pulsed magnetic neuromodulation, per day; **OR**
 - Biofeedback training; **OR**
 - The evaluation by the therapist is non-covered when it is for a non-covered service (e.g., pre-surgical evaluations for the purpose of teaching a home exercise plan and giving assistive device instruction prior to a scheduled surgical procedure are not covered); **OR**
 - Group therapy in the home; **OR**
 - Development of cognitive skills to improve attention, memory, problem-solving, (includes compensatory training), direct (one-on-one) patient contact by the provider, each 15 minutes; **OR**
 - Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact by the provider, each 15 minutes; **OR**

- Work hardening/conditioning; **OR**
- With electrical stimulation; **OR**
- Acupuncture, one or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient; with or without re-insertion of needle(s); **OR**
- Therapeutic procedures for **ANY** of the following regarding the respiratory system:
 - To improve respiratory function or increase strength or endurance of respiratory muscles, one-on-one, face-to-face, per 15 minutes (including monitoring); **OR**
 - To improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (including monitoring); **OR**
- Electrical stimulation, (attended or unattended) to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a POC; **OR**
- Unattended electrical stimulation; **OR**
- Temporomandibular joint (TMJ) pain; **OR**
- Pelvic floor dysfunction (e.g., pelvic floor congestion, pelvic floor relaxation disorders).

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
G0157	Services performed by a qualified physical therapist assistant in the home health or hospice setting, each 15 minutes
G0158	Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes
G0159	Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes
G0160	Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes
G0152	Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes
S9129	Occupational therapy, in the home, per diem
S9131	Physical therapy; in the home, per diem

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

The potential clinical harms of using these criteria for **home physical and occupational therapy (PT/OT)** may include:

- Patients receiving home health care are at risk for infections such as urinary tract infections, respiratory infections, and wound-site infections, which can lead to hospitalization.^{[10](#)}
- Informal caregivers may face challenges in managing complex medical tasks, leading to potential patient safety concerns.^{[10](#)}
- Patients in rural regions may receive fewer PT visits, potentially hindering optimal functional recovery.^{[11](#)}
- The effectiveness of home health services can be influenced by the caregiver's ability to perform necessary medical tasks, which may vary widely.^{[10](#)}
- Prolonged physical therapy may increase pain in certain populations, especially among patients who are candidates for surgical interventions.^{[12-14](#)}

The clinical benefits of using these criteria for **home physical and occupational therapy (PT/OT)** may include:

- Home-based physical therapy (PT) may be beneficial for shoulder patients to improve mobility, strength and function for patients with musculoskeletal disorders.^{[12-14](#)}

- Occupational therapy (OT) interventions focusing on the functional and social needs of patients can prevent hospital readmissions by addressing activities of daily living and safety concerns.¹⁵
- Home-based PT contributes to improved patient experiences and quality of life by providing personalized care in a familiar environment.¹⁶
- Higher utilization of home-based PT is associated with significant improvements in patients' ability to perform activities of daily living (ADLs).¹¹
- OT practitioners develop individualized care plans that address specific functional needs in the home setting, promoting better health outcomes.¹⁵
- Home health services can educate and support caregivers, enhancing their ability to assist patients effectively.¹

Medical Evidence

Raj et al (2021) performed a systematic literature review to assess whether home-based occupational therapy (OT) for adults with dementia optimized patients' daily occupations and reduced caregiver burden. Twenty studies in 22 articles met inclusion criteria for reporting the effects of home-based therapy by a qualified occupational therapist for adults with dementia and their informal caregivers. The studies used education and training to assist patients and caregivers in activities of daily living (ADL) tasks. Training included home environmental modifications, task simplification, use of sensory cues, and promotion of daily routines. Caregiver burden was measured either subjectively or objectively with various measures across studies. This systematic review found moderate evidence to support joint interventions for both the patients and their caregivers. Combined interventions were found to enhance occupational performance of patients, reduce caregiver burden, and improve sense of competence among both groups. Overall, this review found that home-based OT can alleviate burden for caregivers and promote productivity and leisure activities for adults with dementia.²⁰

Chi et al (2020) evaluated the effects of home-based rehabilitation on improvements in physical function in home-dwelling patients after a stroke. This systematic literature review found 49 articles reporting randomized controlled trials that studied these effects. A sensitivity analysis showed that home-based rehabilitation led to moderate improvements in physical function, notably in patients with stroke at a younger age, one stroke episode, acute stage (within 6 months of stroke onset), male sex, and who were receiving the training from their caregiver. This review underscores the importance of home rehabilitation in patients with a history of stroke, as physical function outcomes can significantly improve with home therapy.²¹

Stolee et al (2012) performed a systematic literature review to compare outcomes of home-based versus inpatient rehabilitation in older patients with musculoskeletal conditions. This review captured 8 randomized controlled trials and 4 cohort studies. Among the 12 studies, older patients who received rehabilitation or physical therapy in the home had equal to or

better improvements in function, cognition, quality of life, and satisfaction compared with the inpatient group. This review highlights that home-based rehabilitation may be as effective if not superior to hospital-based rehabilitation.^{[22](#)}

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Version 1.1	10/21/2025	CMS update of L33942, effective 08/07/2025- (CMS annual review, no changes to coverage) Updated LCD link and reference Updated links for Billing and Coding Articles (A57311, A53057) related to update for 10/01/2025 Updated template to current version



Cohere Medicare Advantage Policy – Home Physical and Occupational Therapy (PT/OT)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: April 10, 2025

Important Notices

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Medical Necessity Criteria

Service: Home Physical and Occupational Therapy (PT/OT)

Benefit Category

Not applicable.

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.^{1,2}

- [Local Coverage Determination \(LCD\). Physical therapy – home health \(L33942\).](#)
 - [Billing and Coding: Physical therapy – home health \(A57311\).](#)
- [Local Coverage Determination \(LCD\). Home health occupational therapy \(L34560\).](#)
 - [Billing and Coding: Home health occupational therapy \(A53057\).](#)

Recommended Clinical Approach

For patients with complex medical needs, services such as physical therapy or occupational therapy may be best conducted in a home setting. Home physical therapy and occupational therapy, for example, may treat people with developmental or congenital disabilities, those with chronic conditions, or those in rehabilitation and recovery from an injury or illness. These services help patients regain function and independence, complete household tasks, and engage in personal care. Home health may be recommended as a midpoint level of care between independent living and inpatient hospitalization. It may also facilitate access to care for rural patients or those who would be safer at home than attempting transport to an outpatient facility. Home health is utilized across the age continuum, from medically complex babies to adults of advanced age. Home health is cost-effective, convenient, and effective among appropriately selected patients.¹⁻⁹

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of home physical therapy or occupational therapy. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Patients receiving home health care are at risk for infections such as urinary tract infections, respiratory infections, and wound-site infections, which can lead to hospitalization.^{[10](#)}
- Informal caregivers may face challenges in managing complex medical tasks, leading to potential patient safety concerns.^{[10](#)}
- Patients in rural regions may receive fewer PT visits, potentially hindering optimal functional recovery.^{[11](#)}
- The effectiveness of home health services can be influenced by the caregiver's ability to perform necessary medical tasks, which may vary widely.^{[10](#)}
- Prolonged physical therapy may increase pain in certain populations, especially among patients who are candidates for surgical interventions.^{[12-14](#)}

The clinical benefits of using these criteria include:

- Home-based physical therapy (PT) may be beneficial for shoulder patients to improve mobility, strength and function for patients with musculoskeletal disorders.^{[12-14](#)}
- Occupational therapy (OT) interventions focusing on the functional and social needs of patients can prevent hospital readmissions by addressing activities of daily living and safety concerns.^{[15](#)}
- Home-based PT contributes to improved patient experiences and quality of life by providing personalized care in a familiar environment.^{[16](#)}

- Higher utilization of home-based PT is associated with significant improvements in patients' ability to perform activities of daily living (ADLs).¹¹
- OT practitioners develop individualized care plans that address specific functional needs in the home setting, promoting better health outcomes.¹⁵
- Home health services can educate and support caregivers, enhancing their ability to assist patients effectively.¹

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Home health physical therapy or occupational therapy services** are considered appropriate if **ALL** of the following are **TRUE**:

◆ **ANY** of the following^{3,4,7,8}:

- In order to leave the home, the patient requires the help of another person or medical equipment such as crutches, a walker, or a wheelchair; **OR**
- Receiving medical services outside the home would expose the patient to substantial medical risk; **AND**

◆ It is difficult for the patient to leave the home and they typically cannot do so (e.g., the patient is considered homebound)*; **AND**

◆ Therapy services are provided or supervised by a qualified physical or occupational therapist, and the service was referred to by the patient's physician^{1,2,9}; **AND**

◆ After the patient begins receiving home healthcare, a physician evaluates and recertifies the plan of care (POC) every 60 days

including **ALL** of the following^{17,18}:

- Short- and long-term goals with documentation on how goals will be obtained; **AND**
- An estimated time of when goals are expected to be attained; **AND**
- Measurable objectives; **AND**
- The number of visits requested is appropriate for the diagnosis; **AND**
- Therapy interventions to be used; **AND**

◆ **ANY** of the following is **TRUE**:

- The service is for physical therapy, and **ALL** of the following:
 - The POC addresses specific therapeutic goals and documents the patient's functional limitations in terms that are objective and measurable¹; **AND**
 - The POC addresses the condition for which physical therapy is an accepted method of treatment (may be a functional diagnosis, not necessarily a clinical diagnosis, as defined by standards of medical practice), with the expectation that the condition will improve significantly in a reasonable period of time¹; **AND**
 - Reasonable and necessary to the treatment of the illness or injury, or to the restoration or maintenance of function affected by the illness or injury¹; **AND**
 - The service addresses objective measurements of balance, strength, coordination, or mobility as well as functional limitations of the patient's condition¹; **AND**
 - Treatment notes should be completed per visit. They should be legible and clearly relate back to the established goals. Symbols, acronyms, and notation used in treatment notes should be consistent with standard documentation and discernable, either on their face or by supplied legends¹; **AND**
 - The functional progress should be assessed at the end of the prescribed number of visits; if no progress, the reason for lack of progress and/or alternative treatment strategy should be documented¹; **OR**

- The service is for occupational therapy, and **ALL** of the following:
 - The service is contingent upon the patient's need for occupational therapy, whether the goal includes maintenance or improvement²; **AND**
 - The POC addresses specific therapeutic goals and documents the patient's functional limitations in terms that are objective and measurable²; **AND**
 - The POC addresses the diagnosis(es), treatment goals, duration, and frequency of services²; **AND**
 - The service is **ANY** of the following²:
 - ◆ The service is an initial evaluation, and **ALL** of the following:
 - The patient has a new diagnosis or the condition is being treated in a new setting (e.g., from inpatient to home); **AND**
 - Objective measurements of activities of daily living ([ADLs] e.g., eating, swallowing, bathing, dressing, toileting, walking, climbing stairs); **AND**
 - Evaluations of clinical findings (e.g., chronicity/severity of the problem, the possibility of multi-system involvement or pre-existing conditions); **AND**
 - The extent and duration of loss of function, prior functional level, social/environmental considerations, educational level, the patient's overall physical and cognitive health status, social/cultural supports, psychosocial factors, or use of adaptive equipment; **OR**
 - ◆ The service is a continued treatment²; **OR**
 - ◆ The service is maintenance therapy to maintain the patient's current condition or prevent or slow further deterioration, even if no improvement is expected²; **OR**
 - ◆ The service is a re-evaluation, and **ALL** of the following²:

- The professional assessment indicates progress toward current goals, a significant decline in the patient's condition or functional status that was not anticipated in the POC, or establishes interventions for newly developed impairments; **AND**
- The professional assessment indicates whether continuing care, modifying goals and/or treatment, or terminating services is appropriate; **AND**
- The service is re-evaluated at least once every 30 days for each therapy discipline; **OR**
- The treatment approach includes **ANY** of the following²:
 - ◆ Basic activities of daily living (BADLs) training; **OR**
 - ◆ Instrumental activities of daily living (IADLs) training; **OR**
 - ◆ Muscle testing, manual; **OR**
 - ◆ Range of motion (ROM) measurements; **OR**
 - ◆ Standardized cognitive performance testing (e.g., Ross Information Processing Assessment, Loewenstein Occupational Therapy Cognitive Assessment [LOTCA], Motor-Free Visual Perception Test [MVPT], Allen Cognitive Test [ACL]); **OR**
 - ◆ Therapeutic exercise; **OR**
 - ◆ Muscle re-education; **OR**
 - ◆ Neuromuscular re-education; **OR**
 - ◆ Cognitive training; **OR**
 - ◆ Perceptual motor training; **OR**
 - ◆ Fine motor coordination/strengthening/coordination; **OR**
 - ◆ Orthotics fitting/training (splinting, casting, strapping); **OR**

- ◆ Adaptive equipment fabrication and training; **OR**
- ◆ Environment modification; **OR**
recommendations/training; **OR**
- ◆ Patient/caregiver education/training; **OR**
- ◆ Transfer training; **OR**
- ◆ Functional mobility training; **OR**
- ◆ Manual therapy; **OR**
- ◆ Massage therapy; **OR**
- ◆ Ultrasound; **OR**
- ◆ Physical agent modalities; **OR**
- ◆ Neurodevelopment training; **OR**
- ◆ Rehabilitation services for vision impairment or blindness; **OR**
- ◆ Biofeedback training; **OR**
- ◆ Oral or pharyngeal swallowing function evaluation**; **OR**
- ◆ Swallowing dysfunction and/or oral function for feeding treatment.

*NOTE: Even if a patient is homebound, they can still leave the home for medical treatment, religious services, or to attend an adult day care center without putting their homebound status at risk. Leaving home for short periods of time or for special non-medical events, such as a family reunion, funeral, or graduation, should also not affect homebound status. The patient may also take occasional trips to the barber or beauty parlor.

**NOTE: The evaluation of oropharyngeal swallowing dysfunction may include: history of patient's disorder and awareness of swallowing disorder, and indications of localization and nature of disorder; medical status including nutritional and respiratory status; oral anatomy/physiology (labial control, lingual control, palatal function); pharyngeal function; laryngeal function; ability to follow directions, alertness; efforts and interventions used to facilitate normal swallow (compensatory strategies such as chin tuck, dietary changes, etc.); or identifying symptoms during attempts to swallow. The clinical examination can be divided into 2 phases: the preparatory examination with no swallow; the initial swallow examination with actual

swallow while physiology is observed. Based on the findings, an instrumental exam may be recommended.

Non-Indications

→ **Home health physical therapy or occupational therapy services** are not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Services are custodial in nature (i.e., nonmedical services to assist with daily living and independence)⁵; **OR**
- ◆ Services are solely requested for the comfort or convenience of the caregiver or family member versus the medical necessity of the patient¹⁹; **OR**
- ◆ The patient suffered a temporary loss or reduction of function and could reasonably be expected to improve over time without the services of the therapist¹²; **OR**
- ◆ Therapy that duplicates services that are provided concurrently by any other type of therapy, such as speech and language therapy, should provide different treatment goals, plans, and therapeutic modalities¹²; **OR**
- ◆ The service is for physical therapy, and **ANY** of the following¹:
 - The service is provided routinely to identify if the patient might need or benefit from physical therapy; **OR**
 - The service is related to activities for the general physical welfare of the patient (e.g., to promote overall fitness); **OR**
 - Treatment for incontinence, pulsed magnetic neuromodulation, per day; **OR**
 - Biofeedback training; **OR**
 - The evaluation by the therapist is non-covered when it is for a non-covered service (e.g., pre-surgical evaluations for the purpose of teaching a home exercise plan and giving assistive device instruction prior to a scheduled surgical procedure are not covered); **OR**
 - Group therapy in the home; **OR**
 - Development of cognitive skills to improve attention,

memory, problem-solving, (includes compensatory training), direct (one-on-one) patient contact by the provider, each 15 minutes; **OR**

- Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact by the provider, each 15 minutes; **OR**
- Work hardening/conditioning; **OR**
- With electrical stimulation; **OR**
- Acupuncture, one or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient; with or without re-insertion of needle(s); **OR**
- Therapeutic procedures for **ANY** of the following regarding the respiratory system:
 - To improve respiratory function or increase strength or endurance of respiratory muscles, one-on-one, face-to-face, per 15 minutes (including monitoring); **OR**
 - To improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (including monitoring); **OR**
- Electrical stimulation, (attended or unattended) to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a POC; **OR**
- Unattended electrical stimulation; **OR**
- Temporomandibular joint (TMJ) pain; **OR**
- Pelvic floor dysfunction (e.g., pelvic floor congestion, pelvic floor relaxation disorders).

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
G0157	Services performed by a qualified physical therapist assistant in the home health or hospice setting, each 15 minutes
G0158	Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes
G0159	Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes
G0160	Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes
G0152	Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes
S9129	Occupational therapy, in the home, per diem
S9131	Physical therapy; in the home, per diem

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Raj et al (2021) performed a systematic literature review to assess whether home-based occupational therapy (OT) for adults with dementia optimized patients' daily occupations and reduced caregiver burden. Twenty studies in 22 articles met inclusion criteria for reporting the effects of home-based therapy by a qualified occupational therapist for adults with dementia and their informal caregivers. The studies used education and training to assist patients and caregivers in activities of daily living (ADL) tasks. Training included home environmental modifications, task simplification, use of sensory cues, and promotion of daily routines. Caregiver burden was measured either subjectively or objectively with various measures across studies. This systematic review found moderate evidence to support joint interventions for both the patients and their caregivers. Combined interventions were found to enhance occupational performance of patients, reduce caregiver burden, and improve sense of competence among both groups. Overall, this review found that home-based OT can alleviate burden for caregivers and promote productivity and leisure activities for adults with dementia.²⁰

Chi et al (2020) evaluated the effects of home-based rehabilitation on improvements in physical function in home-dwelling patients after a stroke. This systematic literature review found 49 articles reporting randomized controlled trials that studied these effects. A sensitivity analysis showed that home-based rehabilitation led to moderate improvements in physical function, notably in patients with stroke at a younger age, one stroke episode, acute stage (within 6 months of stroke onset), male sex, and who were receiving the training from their caregiver. This review underscores the importance of home rehabilitation in patients with a history of stroke, as physical function outcomes can significantly improve with home therapy.²¹

Stolee et al (2012) performed a systematic literature review to compare outcomes of home-based versus inpatient rehabilitation in older patients with musculoskeletal conditions. This review captured 8 randomized controlled trials and 4 cohort studies. Among the 12 studies, older patients who received rehabilitation or physical therapy in the home had equal to or

better improvements in function, cognition, quality of life, and satisfaction compared with the inpatient group. This review highlights that home-based rehabilitation may be as effective if not superior to hospital-based rehabilitation.^{[22](#)}

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Clinical Guideline Revision History/Information

Original Date: April 10, 2025		
Review History		

Cohere Medical Policy – Home Physical and Occupational Therapy (PT/OT)

Clinical Policy for Medical Necessity Review

CHP-086-2 Version 2

Cohere UMC Approval Date: April 21, 2026

Last Annual Review: April 21, 2026

Revision Date: Not applicable

Next Annual Review: April 21, 2027

Specialty: Home Health

Population Type: Adult (18+ years old), Pediatric (0-17 years old)

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Procedure Codes (CPT/HCPCS)

Service: Home Physical and Occupational Therapy (PT/OT)	
Code	Description
G0152	Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes
G0157	Services performed by a qualified physical therapist assistant in the home health or hospice setting, each 15 minutes
G0158	Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes
G0159	Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes
G0160	Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes
S9129	Occupational therapy, in the home, per diem
S9131	Physical therapy; in the home, per diem

Important Notices

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Service: Home Physical and Occupational Therapy (PT/OT) - Description

Broadly, physical therapy (PT) is the diagnosis and management of movement deficits or disorders through examination, evaluation, referral, consultation, and intervention. PT can include restoring, maintaining, or promoting bodily function and purposeful action appropriate to the patient's age and development.^{1,2} PT consists of a prescribed program to relieve symptoms, improve function, and prevent decline or disability. Occupational therapy involves evaluation, diagnosis, treatment planning, and interventions to support the development, recovery, or maintenance of skills required for age-appropriate self-care, work, education, and community participation.³ Occupational therapy interventions include task-specific training, education, environmental modifications, and adaptive technologies.

For patients with complex medical needs, PT and OT services may be best delivered in a home setting. These services help patients regain function and independence, complete household tasks, and engage in personal care. A home setting for PT and OT services may be recommended as a midpoint level of care between independent living and inpatient hospitalization.^{4,5}

Service: Home Physical and Occupational Therapy (PT/OT) - Medical Necessity Criteria

Administrative Guidelines for Medical Necessity Review

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Indications

- **Home physical and occupational therapy (PT/OT)** is considered appropriate if **ALL** of the following are **TRUE**:
 - Confined to the home by **ANY** of the following⁶⁻⁹:
 - Requires the help of another person or medical equipment (e.g., cane, crutches, walker, wheelchair)^{5,6}; **OR**
 - Leaving home is medically contraindicated; **AND**
 - **ALL** of the following:
 - Leaving home is difficult and requires significant effort such that patient cannot regularly do so (e.g., the patient is considered homebound)^{7,9}; **AND**
 - Therapy services are provided or supervised by a qualified physical or occupational therapist¹⁰⁻¹²; **AND**
 - Treating physician (or another healthcare provider practicing within the scope of their license) evaluates and recertifies the plan of care (POC) every 60 days, including **ALL** of the following¹⁰:
 - Short- and long-term goals, including measurable objectives^{10,11,13}; **AND**
 - Estimated time by which goals will be met; **AND**
 - Number of visits requested (i.e., appropriate for the diagnosis); **AND**
 - Treatment interventions to be used^{10,11}; **AND**
 - **ANY** of the following^{2,5,8,10,12-20}:
 - Initial treatment with **ANY** of the following¹¹:

- ☐ Functional mobility deficit (e.g., range of motion limitations)¹¹; **OR**
- ☐ Inability to do basic activities of daily living (ADLs) (e.g., bathing, dressing, eating, etc.)^{8,11,13,21}; **OR**
- ☐ Inability to do instrumental ADLs (IADLs) (e.g., housekeeping, managing finances, preparing food)^{8,13,21}; **OR**
- ☐ Signs and symptoms of deterioration or impairment in **ANY** of the following areas⁸:
 - ▲ Motor ability (ergonomics and body mechanics, joint integrity and mobility, muscle performance, neuromotor development, or posture)^{5,8,11,12}; **OR**
 - ▲ Sensation (e.g., problems with sensory integration, cranial or peripheral nerve integrity)^{8,21}; **OR**
 - ▲ Skin and circulation (e.g., integumentary integrity)¹⁵; **OR**
- Continued treatment with intermittent progress notes documenting **ALL** of the following:
 - ☐ Dates of care¹⁰; **AND**
 - ☐ Measures of function at the beginning of the progress report period; **AND**
 - ☐ Current function compared to baseline measures and/or any prior progress reports¹¹; **AND**
 - ☐ **ANY** of the following:
 - ▲ Documented progress related to treatment goals with clinical expectation of continued improvement (i.e., continued services are medically necessary); **OR**
 - ▲ Description of lack of progress and rationale for changes in prognosis, POC, and goals; **OR**
- Re-evaluation and **ALL** of the following¹⁰:
 - ☐ New condition or significant, unanticipated change in functional status; **AND**
 - ☐ Objective measures appropriate for the new or changed condition or impairment^{11,21}; **AND**
 - ☐ Documentation of **ALL** of the following:
 - ▲ Number of therapy visits authorized and/or number of therapy visits attended; **AND**
 - ▲ Description of the patient's current deficits and the severity level based on objective data^{11,21}; **AND**
 - ▲ Objective demonstration of the patient's progress toward each treatment goal, including **ALL** of the following:
 - △ Using consistent and comparable methods to report progress on established long- and short-term treatment goals^{11,21}; **AND**
 - △ For all unmet goals, baseline and current function should be used to measure the patient's progress toward goals; **AND**
 - △ Updated statement of the prescribed treatment modalities and their recommended frequency/duration; **AND**
 - △ Updated or revised POC must include updated measurable, functional, short- and long-term goals, including **ALL** of the following:
 - ◆ If the majority of the long- and short-term goals were not achieved, the POC should include a description of the barriers or an explanation of why the goal(s) needed to be modified or discontinued; **AND**
 - ◆ The notation of progress towards the patient's goals must be in combination with the other indications.

Non-Indications

- **Home physical and occupational therapy (PT/OT)** is not considered appropriate if **ANY** of the following is **TRUE**:
 - Services are custodial (i.e., nonmedical services to assist with daily living and independence); **OR**
 - Services are for the comfort or convenience of the caregiver or family member and not medically necessary for the patient; **OR**
 - Services are solely requested due to lack of suitable transportation; **OR**

- Any non-diagnostic, non-therapeutic, routine, or repetitive services that do not require the skilled intervention of a licensed physical or occupational therapist; **OR**
- Duplicate services. If a patient is prescribed both PT and OT, each therapy should provide different treatment goals, plans of care, and therapeutic interventions^A; **OR**
- Duplicate services from more than one home health agency concurrently.

Definitions and Notes

^AIf a patient is prescribed both PT and OT, only one of the therapies may address hand strength. If both therapists are treating the same condition on the same body part, this is considered *duplicate services*.

Medical Evidence

Ge et al. (2024) reported a randomized controlled trial comparing the effectiveness of home-based physical therapy facilitated by a physical therapist in the patient's home to telerehabilitation consisting of a predetermined exercise program selected for each patient by a physiatrist in 190 patients with mild to moderate Parkinson's disease. The authors reported that adherence to the home program was higher than to the telerehabilitation program. Moreover, while telerehabilitation was effective in younger patients, elderly patients enrolled in the home program showed greater improvements in motor examination, balance, and knee extension muscle strength. The authors concluded that while telerehabilitation may be appropriate for younger patients, they suggested physical therapist-facilitated programs in the patient's home may be preferred for both older patients and patients with low program adherence.²²

Raj et al (2021) performed a systematic literature review to assess whether home-based occupational therapy (OT) for adults with dementia optimized patients' daily occupations and reduced caregiver burden. Twenty studies in 22 articles met inclusion criteria for reporting the effects of home-based therapy by a qualified occupational therapist for adults with dementia and their informal caregivers. The studies used education and training to assist patients and caregivers in activities of daily living (ADL) tasks. Training included home environmental modifications, task simplification, use of sensory cues, and promotion of daily routines. Caregiver burden was measured either subjectively or objectively with various measures across studies. This systematic review found moderate evidence supporting joint interventions for both patients and their caregivers. The authors found combined interventions enhanced occupational performance of patients, reduce caregiver burden, and improved a sense of competence among both groups. Overall, this review found that home-based OT can alleviate burden for caregivers and promote productivity and leisure activities for adults with dementia.²³

Chi et.al. (2020) evaluated the effects of home-based rehabilitation on improvements in physical function among home-dwelling patients after stroke. This systematic literature review found 49 articles reporting randomized controlled trials that studied these effects. A sensitivity analysis showed that home-based rehabilitation led to moderate improvements in physical function, notably in patients with stroke at a younger age, one stroke episode, acute stage (within 6 months of stroke onset), male sex, and who were receiving the training from their caregiver. This review underscores the importance of home rehabilitation in patients with a history of stroke, as physical function outcomes can significantly improve with home therapy.²⁴

Stolee et al. (2012) performed a systematic literature review to compare outcomes of home-based versus inpatient rehabilitation in older patients with musculoskeletal conditions. This review captured 8 randomized controlled trials and 4 cohort studies. Among the 12 studies, older patients who received home-based rehabilitation or physical therapy had improvements in function, cognition, quality of life, and satisfaction that were equal to or better than those in the inpatient group. This review highlights that home-based rehabilitation may be as effective, if not superior to, hospital-based rehabilitation.²⁵

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Policy Revision History/Information

Clinical Policy Version	Date	Review History
Version 1	04/10/2025	Original Date.
Version 2	04/21/2026	Annual review. Revised medical necessity criteria to be more concise. Removed non-indications for assistive and mobility devices and work hardening programs. Revised the Medical Evidence section: Removed Medicare references; added updated clinical practice guidelines (APTA) and 2 additional references.



Cohere Medical Policy – Home Physical and Occupational Therapy (PT/OT)

Clinical Policy for Medical Necessity Review

Version: 2

Policy Number: CHP-086-2

Cohere Health UMC Approval Date: April 21, 2026

Last Annual Review: April 21, 2026

Revision: Not Applicable

Next Annual Review: April 21, 2027

Important Notices

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Policy Information:

Specialty Area: Home Health

Policy Name: Cohere Medical Policy - Home Physical and Occupational Therapy (PT/OT)

Policy Number: CHP-086-2

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Home Physical and Occupational Therapy (PT/OT)

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Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
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 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Description

Broadly, physical therapy (PT) is the diagnosis and management of movement deficits or disorders through examination, evaluation, referral, consultation, and intervention. PT can include restoring, maintaining, or promoting bodily function and purposeful action appropriate to the patient's age and development.^{1,2} PT consists of a prescribed program to relieve symptoms, improve function, and prevent decline or disability. Occupational therapy involves evaluation, diagnosis, treatment planning, and interventions to support the development, recovery, or maintenance of skills required for age-appropriate self-care, work, education, and community participation.³ Occupational therapy interventions include task-specific training, education, environmental modifications, and adaptive technologies.

For patients with complex medical needs, PT and OT services may be best delivered in a home setting. These services help patients regain function and independence, complete household tasks, and engage in personal care. A home setting for PT and OT services may be recommended as a midpoint level of care between independent living and inpatient hospitalization.^{4,5}

Medical Necessity Criteria

Indications

Home physical and occupational therapy (PT/OT) is considered appropriate if **ALL** of the following are **TRUE**:

- Confined to the home by **ANY** of the following⁶⁻⁹:
 - Requires the help of another person or medical equipment (e.g., cane, crutches, walker, wheelchair)^{5,6}; **OR**
 - Leaving home is medically contraindicated; **AND**
- **ALL** of the following:
 - Leaving home is difficult and requires significant effort such that patient cannot regularly do so (e.g., the patient is considered homebound)^{A,7,9}; **AND**
 - Therapy services are provided or supervised by a qualified physical or occupational therapist¹⁰⁻¹²; **AND**
 - Treating physician (or another healthcare provider practicing within the scope of their license) evaluates and recertifies the plan of care (POC) every 60 days, including **ALL** of the following¹⁰:
 - Short- and long-term goals, including measurable objectives^{10,11,13}; **AND**
 - Estimated time by which goals will be met; **AND**
 - Number of visits requested (i.e., appropriate for the diagnosis); **AND**
 - Treatment interventions to be used^{10,11}; **AND**
- **ANY** of the following^{2,5,8,10,12-20}:
 - Initial treatment with **ANY** of the following¹¹:
 - Functional mobility deficit (e.g., range of motion limitations)¹¹; **OR**
 - Inability to do basic activities of daily living (ADLs) (e.g., bathing, dressing, eating, etc.)^{8,11,13,21}; **OR**
 - Inability to do instrumental ADLs (IADLs) (e.g., housekeeping, managing finances, preparing food)^{8,13,21}; **OR**
 - Signs and symptoms of deterioration or impairment in **ANY** of the following areas⁸:
 - Motor ability (ergonomics and body mechanics, joint integrity and mobility, muscle performance, neuromotor development, or posture)^{5,8,11,12}; **OR**
 - Sensation (e.g., problems with sensory integration, cranial or peripheral nerve integrity)^{8,21}; **OR**
 - Skin and circulation (e.g., integumentary integrity)¹⁵; **OR**

- Continued treatment with intermittent progress notes documenting **ALL** of the following:
 - Dates of care¹⁰; **AND**
 - Measures of function at the beginning of the progress report period; **AND**
 - Current function compared to baseline measures and/or any prior progress reports¹¹; **AND**
 - **ANY** of the following:
 - Documented progress related to treatment goals with clinical expectation of continued improvement (i.e., continued services are medically necessary); **OR**
 - Description of lack of progress and rationale for changes in prognosis, POC, and goals; **OR**
- Re-evaluation and **ALL** of the following¹⁰:
 - New condition or significant, unanticipated change in functional status; **AND**
 - Objective measures appropriate for the new or changed condition or impairment^{11,21}; **AND**
 - Documentation of **ALL** of the following:
 - Number of therapy visits authorized and/or number of therapy visits attended; **AND**
 - Description of the patient's current deficits and the severity level based on objective data^{11,21}; **AND**
 - Objective demonstration of the patient's progress toward each treatment goal, including **ALL** of the following:
 - Using consistent and comparable methods to report progress on established long- and short-term treatment goals^{11,21}; **AND**
 - For all unmet goals, baseline and current function should be used to measure the patient's progress toward goals; **AND**
 - Updated statement of the prescribed treatment modalities and their recommended frequency/duration; **AND**
 - Updated or revised POC must include updated measurable, functional, short- and long-term goals, including **ALL** of the following:
 - If the majority of the long- and short-term goals were not achieved, the POC should include a description of the barriers or an explanation of why the goal(s) needed to be modified or discontinued; **AND**

- The notation of progress towards the patient's goals must be in combination with the other indications.

Non-Indications

Home physical and occupational therapy (PT/OT) is not considered appropriate if **ANY** of the following is **TRUE**:

- Services are custodial (i.e., nonmedical services to assist with daily living and independence); **OR**
- Services are for the comfort or convenience of the caregiver or family member and not medically necessary for the patient; **OR**
- Services are solely requested due to lack of suitable transportation; **OR**
- Any non-diagnostic, non-therapeutic, routine, or repetitive services that do not require the skilled intervention of a licensed physical or occupational therapist; **OR**
- Duplicate services. If a patient is prescribed both PT and OT, each therapy should provide different treatment goals, plans of care, and therapeutic interventions^B; **OR**
- Duplicate services from more than one home health agency concurrently.

Definitions and Notes

^APer the [CMS benefit policy manual](#), if a person is considered *homebound*, they may still leave the home for therapeutic, psychosocial, and medical appointments or treatment, or to attend an adult day care center, without risking their homebound status. Leaving home for short periods for non-medical events, such as a funeral or graduation, should not affect homebound status. Similarly, the patient may take occasional trips for personal care, such as a visit to the barber or beauty parlor.

^BIf a patient is prescribed both PT and OT, only one of the therapies may address hand strength. If both therapists are treating the same condition on the same body part, this is considered *duplicate services*.

^C*S codes* are temporary national codes that may not be payable according to each plan's coverage policies.

Procedure Codes (CPT/HCPCS)^c

CPT/HCPCS Code	Code Description
G0152	Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes
G0157	Services performed by a qualified physical therapist assistant in the home health or hospice setting, each 15 minutes
G0158	Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes
G0159	Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes
G0160	Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes
S9129	Occupational therapy, in the home, per diem
S9131	Physical therapy; in the home, per diem

Medical Evidence

Ge et al. (2024) reported a randomized controlled trial comparing the effectiveness of home-based physical therapy facilitated by a physical therapist in the patient's home to telerehabilitation consisting of a predetermined exercise program selected for each patient by a physiatrist in 190 patients with mild to moderate Parkinson's disease. The authors reported that adherence to the home program was higher than to the telerehabilitation program. Moreover, while telerehabilitation was effective in younger patients, elderly patients enrolled in the home program showed greater improvements in motor examination, balance, and knee extension muscle strength. The authors concluded that while telerehabilitation may be appropriate for younger patients, they suggested physical therapist-facilitated programs in the patient's home may be preferred for both older patients and patients with low program adherence.²²

Raj et al (2021) performed a systematic literature review to assess whether home-based occupational therapy (OT) for adults with dementia optimized patients' daily occupations and reduced caregiver burden. Twenty studies in 22 articles met inclusion criteria for reporting the effects of home-based therapy by a qualified occupational therapist for adults with dementia and their informal caregivers. The studies used education and training to assist patients and caregivers in activities of daily living (ADL) tasks. Training included home environmental modifications, task simplification, use of sensory cues, and promotion of daily routines. Caregiver burden was measured either subjectively or objectively with various measures across studies. This systematic review found moderate evidence supporting joint interventions for both patients and their caregivers. The authors found combined interventions enhanced occupational performance of patients, reduce caregiver burden, and improved a sense of competence among both groups. Overall, this review found that home-based OT can alleviate burden for caregivers and promote productivity and leisure activities for adults with dementia.²³

Chi et.al. (2020) evaluated the effects of home-based rehabilitation on improvements in physical function among home-dwelling patients after stroke. This systematic literature review found 49 articles reporting

randomized controlled trials that studied these effects. A sensitivity analysis showed that home-based rehabilitation led to moderate improvements in physical function, notably in patients with stroke at a younger age, one stroke episode, acute stage (within 6 months of stroke onset), male sex, and who were receiving the training from their caregiver. This review underscores the importance of home rehabilitation in patients with a history of stroke, as physical function outcomes can significantly improve with home therapy.²⁴

Stolee et al. (2012) performed a systematic literature review to compare outcomes of home-based versus inpatient rehabilitation in older patients with musculoskeletal conditions. This review captured 8 randomized controlled trials and 4 cohort studies. Among the 12 studies, older patients who received home-based rehabilitation or physical therapy had improvements in function, cognition, quality of life, and satisfaction that were equal to or better than those in the inpatient group. This review highlights that home-based rehabilitation may be as effective, if not superior to, hospital-based rehabilitation.²⁵

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Policy Revision History/Information

Original Date: April 10, 2025		
Review History		
Version 2	04/21/2026	Annual review. Revised medical necessity criteria to be more concise. Removed non-indications for assistive and mobility devices and work hardening programs. Revised the Medical Evidence section: Removed Medicare references; added updated clinical practice guidelines (APTA) and 2 additional references.



Cohere Medical Policy - Home Physical and Occupational Therapy (PT/OT)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: April 10, 2025

Important Notices

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Guideline Name: Cohere Medical Policy - Home Physical and Occupational Therapy (PT/OT)

Date of last literature review: 4/3/2025

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Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Home Physical and Occupational Therapy (PT/OT)

Recommended Clinical Approach

For patients with complex medical needs, services such as physical therapy or occupational therapy may be best conducted in a home setting. Home physical therapy and occupational therapy, for example, may treat people with developmental or congenital disabilities, those with chronic conditions, or those in rehabilitation and recovery from an injury or illness. These services help patients regain function and independence, complete household tasks, and engage in personal care. Home health may be recommended as a midpoint level of care between independent living and inpatient hospitalization. It may also facilitate access to care for rural patients or those who would be safer at home than attempting transport to an outpatient facility. Home health is utilized across the age continuum, from medically complex babies to adults of advanced age. Home health is cost-effective, convenient, and effective among appropriately selected patients.¹⁻⁷

Medical Necessity Criteria

Indications

→ **Home health physical therapy or occupational therapy services** are considered appropriate if **ALL** of the following are **TRUE**:

◆ **ANY** of the following^{1,2,5,6}:

- In order to leave the home, the patient requires the help of another person or medical equipment such as crutches, a walker, or a wheelchair; **OR**
- Receiving medical services outside the home would expose the patient to substantial medical risk; **AND**

◆ It is difficult for the patient to leave the home and they typically cannot do so (e.g., the patient is considered homebound)*; **AND**

◆ Therapy services are provided or supervised by a qualified physical or occupational therapist⁷; **AND**

- ◆ After the patient begins receiving home healthcare, a physician evaluates and recertifies the plan of care (POC) every 60 days including **ALL** of the following:
 - Short- and long-term goals with documentation on how goals will be obtained; **AND**
 - An estimated time of when goals are expected to be attained; **AND**
 - Measurable objectives; **AND**
 - The number of visits requested is appropriate for the diagnosis; **AND**
 - Therapy exercises/techniques to be used; **AND**
- ◆ **ANY** of the following is **TRUE**⁷⁻¹⁸:
 - The service is an initial treatment, and **ANY** of the following:
 - The patient exhibits signs and symptoms of a functional or physical impairment as evidenced by **ANY** of the following:
 - ◆ The inability to perform basic activities of daily living (ADLs) (e.g., functional mobility, feeding, dressing, bathing, or toileting); **OR**
 - ◆ The inability to perform instrumental activities of daily living ([IADLs] e.g., preparing a meal, housekeeping, managing finances); **OR**
 - ◆ The inability to perform other ADLS (e.g., functional mobility limitations, range of motion limitations); **OR**
 - The patient exhibits signs and symptoms of physical deterioration or impairment in **ANY** of the following areas:
 - ◆ Sensory ability (e.g., problems with sensory integration, cranial and peripheral nerve integrity, or sensory integrity); **OR**
 - ◆ Motor ability (range of motion, ergonomics and body mechanics, joint integrity and mobility, motor function, muscle performance, neuromotor development, or posture); **OR**
 - ◆ Skin and circulation (e.g., integumentary integrity or circulation); **OR**

- The service is a continued treatment, and intermittent progress notes demonstrate **ALL** of the following:
 - Start of care date, date of treatment, and time period covered by the report; **AND**
 - The patient's function at the beginning of the progress report period; **AND**
 - The patient's current status as compared to evaluation baseline data and the prior progress reports, including objective measures of patient performance in functional terms that relate to the treatment goals; **AND**
 - The patient is making functional progress related to treatment goals, and they are expected to continue to improve to reflect that continued services are medically necessary; **AND**
 - All progress toward the goals in objective, measurable terms using consistent and comparable methods; **AND**
 - If the patient is not making progress as expected, describe any changes in prognosis, POC, goals, and why; **AND**
 - Consultations with other professionals or coordination of services, if applicable; **OR**
- The service is a re-evaluation for treatment, and **ALL** of the following are **TRUE**:
 - The patient was already receiving therapy and developed a new condition or significant change in functional status that was not anticipated, thus requiring additional evaluation; **AND**
 - The re-evaluation includes current standardized assessment scores, age equivalents, percentage of functional delay, criterion-referenced scores, or other objective information as appropriate for the patient's condition or impairment; **AND**
 - The therapy re-evaluation report should include **ALL** of the following:
 - ◆ Date of last therapy evaluation or re-evaluation; **AND**

- ◆ Number of therapy visits authorized and number of therapy visits attended; **AND**
- ◆ Description of the patient's current deficits and the severity level documented using objective data; **AND**
- ◆ Objective demonstration of the patient's progress toward each treatment goal, including **ANY** of the following:
 - Using consistent and comparable methods to report progress on long- and short-term treatment goals established; **OR**
 - For all unmet goals, baseline and current function should be used to measure the patient's progress toward goals; **AND**
- ◆ An updated statement of the prescribed treatment modalities and their recommended frequency/duration; **AND**
- ◆ An updated or revised POC must include updated measurable, functional, and time-based goals, including **ALL** of the following:
 - If the majority of the long and short-term goals were not achieved, the POC should include a description of the barriers or an explanation of why the goal(s) needed to be modified or discontinued; **AND**
 - The notation of the percentage accuracy towards the patient's goals must be in combination with the other indications.

*NOTE: Even if a patient is homebound, they can still leave the home for medical treatment, religious services, or to attend an adult day care center without putting their homebound status at risk. Leaving home for short periods of time or for special non-medical events, such as a family reunion, funeral, or graduation, should also not affect homebound status. The patient may also take occasional trips to the barber or beauty parlor.

Non-Indications

→ **Home health physical therapy or occupational therapy services** are not considered appropriate if **ANY** of the following is **TRUE**:

- ◆ Services are custodial in nature (i.e., nonmedical services to assist with daily living and independence)³; **OR**
- ◆ Services are solely requested for the comfort or convenience of the caregiver or family member versus the medical necessity of the patient¹⁹; **OR**
- ◆ **ANY** of the following⁷⁻¹⁸:
 - Unattended electrical stimulation when used for peripheral neuropathy; **OR**
 - Work hardening and conditioning; **OR**
 - Assistive and mobility devices to assist with functional abilities and activities of daily living; **OR**
 - Low-level laser therapy (e.g., nonthermal and non-ablative) for post-operative pain reduction; **OR**
 - Maintenance therapy, including services that involve non-diagnostic, non-therapeutic, routine, or repetitive procedures to maintain general welfare and do not require the skilled assistance of a licensed physical or occupational therapist (the establishment of a maintenance program, and the training of the patient, patient's family, or other persons to carry it out is reimbursed as part of a regular treatment visit, not as a separate service); **OR**
 - Therapy that duplicates services that are provided concurrently by any other type of therapy, such as PT and speech and language therapy, which should provide different treatment goals, plans, and therapeutic modalities.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
G0157	Services performed by a qualified physical therapist assistant in the home health or hospice setting, each 15 minutes
G0158	Services performed by a qualified occupational therapist assistant in the home health or hospice setting, each 15 minutes
G0159	Services performed by a qualified physical therapist, in the home health setting, in the establishment or delivery of a safe and effective physical therapy maintenance program, each 15 minutes
G0160	Services performed by a qualified occupational therapist, in the home health setting, in the establishment or delivery of a safe and effective occupational therapy maintenance program, each 15 minutes
G0152	Services performed by a qualified occupational therapist in the home health or hospice setting, each 15 minutes
S9129	Occupational therapy, in the home, per diem
S9131	Physical therapy; in the home, per diem

Medical Evidence

Raj et al (2021) performed a systematic literature review to assess whether home-based occupational therapy (OT) for adults with dementia optimized patients' daily occupations and reduced caregiver burden. Twenty studies in 22 articles met inclusion criteria for reporting the effects of home-based therapy by a qualified occupational therapist for adults with dementia and their informal caregivers. The studies used education and training to assist patients and caregivers in activities of daily living (ADL) tasks. Training included home environmental modifications, task simplification, use of sensory cues, and promotion of daily routines. Caregiver burden was measured either subjectively or objectively with various measures across studies. This systematic review found moderate evidence to support joint interventions for both the patients and their caregivers. Combined interventions were found to enhance occupational performance of patients, reduce caregiver burden, and improve a sense of competence among both groups. Overall, this review found that home-based OT can alleviate burden for caregivers and promote productivity and leisure activities for adults with dementia.²⁰

Chi et al (2020) evaluated the effects of home-based rehabilitation on improvements in physical function in home-dwelling patients after a stroke. This systematic literature review found 49 articles reporting randomized controlled trials that studied these effects. A sensitivity analysis showed that home-based rehabilitation led to moderate improvements in physical function, notably in patients with stroke at a younger age, one stroke episode, acute stage (within 6 months of stroke onset), male sex, and who were receiving the training from their caregiver. This review underscores the importance of home rehabilitation in patients with a history of stroke, as physical function outcomes can significantly improve with home therapy.²¹

Stolee et al (2012) performed a systematic literature review to compare outcomes of home-based versus inpatient rehabilitation in older patients with musculoskeletal conditions. This review captured 8 randomized controlled trials and 4 cohort studies. Among the 12 studies, older patients who received rehabilitation or physical therapy in the home had equal to or better improvements in function, cognition, quality of life, and satisfaction compared with the inpatient group. This review highlights that home-based rehabilitation may be as effective if not superior to hospital-based rehabilitation.²²

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Cohere Medicare Advantage Policy – Home Health

Clinical Guidelines for Medical Necessity Review

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Medical Necessity Criteria

Service: Home Health

Benefit Category

Extended Care Services

Home Health Services

Inpatient Hospital Services

Outpatient Hospital Services Incident to a Physician's Service

Outpatient Occupational Therapy Services

Outpatient Physical Therapy Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.¹⁻⁹

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.¹⁻⁹

- [National Coverage Determination \(NCD\). Home health nurses' visits to patients requiring heparin injection \(290.2\)](#)
- [National Coverage Determination \(NCD\). Home health visits to a blind diabetic \(290.1\)](#)
- [National Coverage Determination \(NCD\). Institutional and home care patient education programs \(170.1\)](#)
- [Local Coverage Determination \(LCD\). Home health - psychiatric care \(L34561\)](#)
- [Local Coverage Determination \(LCD\). Home health plans of care: monitoring glucose control in the Medicare home health population with type II diabetes mellitus \(L35132\)](#)
- [Local Coverage Determination \(LCD\). Home health skilled nursing care-teaching and training: Alzheimer's disease and behavioral disturbances \(L34562\)](#)
- [Billing and Coding: Home health skilled nursing care-teaching and training: Alzheimer's disease and behavioral disturbances \(A56641\).](#)

- [Billing and Coding: Home health plans of care: monitoring glucose control in the Medicare home health population with type II diabetes mellitus \(A56674\).](#)
- [Billing and Coding: Home health – psychiatric care \(A57756\).](#)

Recommended Clinical Approach

Home health aims to prevent the onset of illness or injury (i.e., nosocomial infection, etc.), ameliorate the physical, mental, and developmental consequences of an injury, illness, or disability, and support an individual in attaining maximum functional capacity. As a cost-saving measure, home health mitigates the need for expensive, long-term institutional or inpatient care – particularly for patients with chronic illness, permanent injuries, or end-of-life conditions. Patients are often more comfortable receiving care in a familiar, safe environment, and the home may already be optimized with any appropriate medical equipment and other modifications that the individual patient requires. Home health is a valuable service for transitioning patients from a hospital setting to the home. Common populations that benefit from home healthcare include unstable ventilator-dependent patients, medically complex children, patients who have suffered an acute injury, and other patients for whom independent living and self-care may not be safe or feasible.¹⁻¹⁰

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of home health. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Reduced supervision. In the home setting, inappropriately selected patients who are medically unstable and would benefit more from inpatient care may be inadequately monitored, conferring a potential risk for clinical decompensation or incomplete care. This highlights the importance of careful patient selection for those who require some level of skilled home care but are stable enough not to require formalized inpatient treatment.¹⁰

- Dependence on family members or caregivers. As home health is limited in nature and requires participation from caregivers (often family members) to be successful, the patient must rely on their caregiver to be educated and trained in providing their care. This may result in relationship challenges between patient and caregiver.¹⁰
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Reduced risk of nosocomial infection. Receiving care in the home setting inherently removes the risk of nosocomial infections, including line-associated sepsis, hospital-acquired pneumonia, or viral infections.¹⁰
- Safe, familiar, comfortable environment. Home care allows skilled services to be conducted in an environment that is already familiar to the patient, potentially improving patient participation in care and reducing overall stress levels – particularly among children.¹⁰⁻¹³
- Reduced risk of long-term institutionalization. With the intermittent involvement of skilled professionals in the home setting, primary caregivers may be less likely to institutionalize the patient as they receive tangible support from home health professionals.¹⁰
- Less expensive and burdensome to families and caregivers. As compared to traditional inpatient or outpatient care, home care is generally more affordable and less burdensome to the family, allowing the patient to receive skilled care without requiring transportation beyond the home. This also reduces barriers to accessing care.¹⁰⁻¹³
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

→ **Home health** is considered appropriate if **ALL** of the following are **TRUE**^{1-9,14,15}:

◆ **ANY** of the following:

- In order to leave the home, the patient requires the help of another person or medical equipment such as crutches, a walker, or a wheelchair; **OR**
- Receiving medical services outside the home would expose the patient to substantial medical risk; **AND**

◆ It is difficult for the patient to leave the home and they typically cannot do so (e.g., the patient is considered homebound)*; **AND**

◆ In-home health service is ordered and directed by an attending physician or a health care provider practicing within the scope of their license as part of a written plan of care; **AND**

◆ After the patient begins receiving home healthcare, a physician evaluates and recertifies the plan of care (POC) every 30 days, including **ALL** of the following^{16,17}:

- Short- and long-term goals with documentation on how goals will be obtained; **AND**
- An estimated time of when goals will be attained; **AND**
- Measurable objectives; **AND**
- The number of visits requested is appropriate for the diagnosis; **AND**

◆ The service is inherently complex such that it can only be safely and effectively performed by a qualified technical or professional health personnel such as a registered nurse, a licensed practical (vocational) nurse, a respiratory therapist, or other skilled staff; **AND**

◆ Services are not custodial in nature (i.e., nonmedical services to assist with daily living and independence); **AND**

◆ **ANY** of the following:

- Social work services with **ALL** of the following^{4,16}:

- The social work services are necessary to resolve social or emotional problems which are, or are expected to be, an impediment to the effective treatment of the patient's psychiatric condition or their rate of recovery; **AND**
- The skills of a qualified MSW (Master of Social Work, or a social worker assistant under the supervision of a qualified MSW) are required to safely and effectively provide the needed care; **AND**
- Social work visit for a patient requiring **ANY** of the following:
 - ◆ In-home assessment; **OR**
 - ◆ Care coordination; **OR**
 - ◆ Case management; **OR**
 - ◆ Ongoing emotional or psychosocial support; **OR**
 - ◆ Connection to resources; **OR**
 - ◆ Brief counseling (2 or 3 visits) of the patient's family or caregiver(s) when they are reasonable and necessary⁴; **OR**
- Remote patient monitoring with **ALL** of the following^{18,19}:
 - The requesting provider has an established treating relationship with the patient; **AND**
 - Only one provider may request physiologic monitoring per condition in a 30-day period; **AND**
 - Remote physiologic monitoring and remote therapeutic monitoring may not be requested together; **AND**
 - Monitoring must be medically reasonable and necessary; **AND**
 - Documented shared decision-making between patient and provider; **AND**
 - Physiologic data must be electronically collected and automatically uploaded to a secure location where the data can be available for analysis and interpretation by the requesting provider; **AND**
 - The device used to collect and transmit the data must meet the definition of a medical device as defined by the FDA; **OR**

- Patient or caregiver education for self-administration of subcutaneous low-dose injectable heparin (or administration if patient or caregiver is unable) for **ANY** of the following reasons¹:
 - The patient is pregnant and requires anticoagulant therapy; **OR**
 - The patient requires treatment for deep venous thrombosis or pulmonary emboli or for another condition requiring anticoagulation and documentation justifies that the patient cannot tolerate warfarin; **OR**
- Administration of daily insulin injections for patients who have a documented physical or mental inability to self-inject insulin provided that there is no other person who is able and willing to inject the patient⁵; **OR**
- Telehealthcare as an alternative or supplement to in-person care^{16,19}; **OR**
- Other in-home care that is reasonable and necessary and is intended to meet clinical needs that are well established on medical documentation.

*NOTE: Even if a patient is homebound, they can still leave the home for medical treatment, religious services, or to attend an adult day care center without putting their homebound status at risk. Leaving home for short periods of time or for special non-medical events, such as a family reunion, funeral, or graduation, should also not affect homebound status. The patient may also take occasional trips to the barber or beauty parlor.⁴

Non-Indications

→ **Home health** is not considered appropriate if **ANY** of the following is **TRUE**¹⁻⁶:

- ◆ The treatment plan does not demonstrate a continued need for skilled home care; **OR**
- ◆ Services are custodial in nature (i.e., nonmedical services to assist with daily living and independence); **OR**
- ◆ Services are solely requested for the comfort or convenience of the caregiver or family member versus the medical necessity of the patient; **OR**

- ◆ If the sole purpose of a nurse's visit is to prefill insulin syringes for a blind diabetic²; **OR**
- ◆ Educational activities that are not closely related to the care and treatment of the patient (e.g., a program instructing patients generally in preventive health activities, a program designed to prevent illness by instructing the general public in the importance of good nutritional habits, exercise regimens, and good hygiene, etc.)³; **OR**
- ◆ The services of a social worker are requested to assist in applying for Medicaid or to follow up on the application. Federal regulation requires the state to provide assistance in completing the application to anyone who chooses to apply for Medicaid.⁴

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
G0155	Services of clinical social worker in home health or hospice settings, each 15 minutes
G0162	Skilled services by a registered nurse (RN) for management and evaluation of the plan of care; each 15 minutes (the patient's underlying condition or complication requires an RN to ensure that essential non-skilled care achieves its purpose in the home health or hospice setting)
G0320	Home health services furnished using synchronous telemedicine rendered via a real-time two-way audio and video telecommunications system
G0321	Home health services furnished using synchronous telemedicine rendered via telephone or other real-time interactive audio-only telecommunications system
G0322	The collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency (i.e., remote patient monitoring)

G0493	Skilled services of a registered nurse (RN) for the observation and assessment of the patient's condition, each 15 minutes (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment in the home health or hospice setting)
G0494	Skilled services of a licensed practical nurse (LPN) for the observation and assessment of the patient's condition, each 15 minutes (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment in the home health or hospice setting)
G0495	Skilled services of a registered nurse (RN), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes
G0496	Skilled services of a licensed practical nurse (LPN), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes
S9127	Social work visit, in the home, per diem
G0299	Direct skilled nursing services of a registered nurse (RN) in the home health or hospice setting, each 15 minutes
G0300	Direct skilled nursing services of a licensed practical nurse (LPN) in the home health or hospice setting, each 15 minutes
Q5001	Hospice or home health care provided in patient's home/residence
Q5002	Hospice or home health care provided in assisted living facility
Q5009	Hospice or home health care provided in place not otherwise specified (NOS)

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

A 2022 *JAMA* unblinded randomized controlled trial (RCT) reviewed the outcomes of an intensive home health program on Medicaid-eligible patients. The study included 5,670 Medicaid-eligible nulliparous pregnant individuals under 28 weeks' gestation. Participants were randomized to the intensive home visiting program (n=3806) or usual care (n=1864). Home nursing visits began prenatally and continued for 2 years after birth. Nurses provided in-home assessments and education around prenatal health, child health, and maternal life planning. The primary outcome of adverse birth outcomes (a composite variable comprising preterm birth, low birth weight, small for gestational age, or perinatal mortality) displayed no significant improvement among home health recipients. However, the authors emphasize the fact that, at the time of publication, the remaining primary outcomes (interbirth intervals of less than 21 months and major injury or concern for abuse or neglect in the child's first 24 months), as well as many secondary outcomes relating to long-term maternal and childhood health, had not yet been completed. Hence, the true impact of home visiting services on this population cannot yet be articulated. Importantly, a secondary analysis of this RCT published in December 2024 found a reduction in emergency department utilization in the postpartum period.^{20,21}

In 2021, *JAMA* published a study by Arsenault-Lapierre et al examining the role of home health in reducing the risk of inpatient readmission. This systematic review included 959 patients across 9 RCTs. Patients were community-dwelling, diagnosed with a chronic disease, and received in-home care as an alternative to inpatient treatment. Home health was associated with a 26% reduction, as well as a lower risk of admission to a long-term care (LTC) facility.²²

A 2024 study evaluated patients discharged from Boston Children's Hospital's neonatal intensive care unit (NICU). The authors included 155 parents of infants discharged from the NICU to a home health setting who completed the "NICU to Nursery" pre-discharge and post-discharge assessment and training program. This qualitative study found that visiting nurses most often educated parents on the management of tubes and drains, growth and nutrition, and response to emergency situations.²³

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Clinical Guideline Revision History/Information

Original Date: April 10, 2025		
Review History		



Cohere Medical Policy – Home Health

Clinical Guidelines for Medical Necessity Review

Version: 1
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Important Notices

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Medical Necessity Criteria

Service: Home Health

Recommended Clinical Approach

Home health aims to prevent the onset of illness or injury (i.e., nosocomial infection, etc.), ameliorate the physical, mental, and developmental consequences of an injury, illness, or disability, and support an individual in attaining maximum functional capacity. As a cost-saving measure, home health mitigates the need for expensive, long-term institutional or inpatient care – particularly for patients with chronic illness, permanent injuries, or end-of-life conditions. Patients are often more comfortable receiving care in a familiar, safe environment, and the home may already be optimized with any appropriate medical equipment and other modifications that the individual patient requires. Home health is a valuable service for transitioning patients from a hospital setting to the home. Common populations that benefit from home healthcare include unstable ventilator-dependent patients, medically complex children, patients who have suffered an acute injury, and other patients for whom independent living and self-care may not be safe or feasible.¹⁻⁴

Medical Necessity Criteria

Indications

→ **Home health services** are considered appropriate if **ALL** of the following are **TRUE**¹⁻¹¹:

◆ **ANY** of the following:

- In order to leave the home, the patient requires the help of another person or medical equipment such as crutches, a walker, or a wheelchair; **OR**
- Receiving medical services outside the home would expose the patient to substantial medical risk; **AND**

◆ It is difficult for the patient to leave the home and they typically cannot do so (e.g., the patient is considered homebound)*; **AND**

- ◆ In-home health service is ordered and directed by an attending physician or a health care provider practicing within the scope of their license as part of a written plan of care; **AND**
- ◆ After the patient begins receiving home healthcare, a physician evaluates and recertifies the plan of care (POC) every 30 days, including **ALL** of the following^{12,13}:
 - Short- and long-term goals with documentation on how goals will be obtained; **AND**
 - An estimated time of when goals will be attained; **AND**
 - Measurable objectives; **AND**
 - The number of visits requested is appropriate for the diagnosis; **AND**
- ◆ The service is inherently complex such that it can only be safely and effectively performed by a qualified technical or professional health personnel such as a registered nurse, a licensed practical (vocational) nurse, a respiratory therapist, or other skilled staff; **AND**
- ◆ Services are not custodial in nature (i.e., they are not nonmedical services to assist with daily living and independence); **AND**
- ◆ **ANY** of the following:
 - Social work visit for a patient with **ALL** of the following^{12,14-21}:
 - Another skilled service (intermittent skilled nursing, physical therapy, speech therapy, or occupational therapy) must be occurring in the home setting; **AND**
 - There is an impediment to the patient's recovery that requires the skills of an MSW (Master of Social Work) to remove; **AND**
 - **ANY** of the following:
 - ◆ Assessment of the social and emotional factors related to the patient's illness, need for care, response to treatment, and adjustment to care; **OR**
 - ◆ Assessment of the relationship of the patient's medical and nursing requirements to the patient's home situation, financial resources, and availability of community resources; **OR**
 - ◆ Short-term services (two to three visits) to a family member or caregiver when a brief

intervention is necessary to facilitate recovery;

OR

◆ Counseling services that are required by the patient; **OR**

◆ Appropriate action to obtain the necessary community resources to support recovery; **OR**

● Remote patient monitoring with **ALL** of the following^{22,23}:

- The requesting provider has an established treating relationship with the patient; **AND**
- Only one provider may request physiologic monitoring per condition in a 30-day period; **AND**
- Remote physiologic monitoring and remote therapeutic monitoring may not be requested together; **AND**
- Monitoring must be medically reasonable and necessary; **AND**
- Documented shared decision-making between patient and provider; **AND**
- Physiologic data must be electronically collected and automatically uploaded to a secure location where the data can be available for analysis and interpretation by the requesting provider; **AND**
- The device used to collect and transmit the data must meet the definition of a medical device as defined by the FDA; **OR**

● Telehealthcare as an alternative or supplement to in-person care^{24,25}; **OR**

● Other in-home care that is reasonable and necessary and is intended to meet clinical needs that are well established on medical documentation.

*NOTE: Even if a patient is homebound, they can still leave the home for medical treatment, religious services, or to attend an adult day care center without putting their homebound status at risk. Leaving home for short periods of time or for special non-medical events, such as a family reunion, funeral, or graduation, should also not affect homebound status. The patient may also take occasional trips to the barber or beauty parlor.

Non-Indications

→ **Home health services** are not considered appropriate if **ANY** of the following is **TRUE**¹⁻¹¹:

- ◆ The treatment plan does not demonstrate a continued need for skilled home care; **OR**
- ◆ Services are custodial in nature (i.e., nonmedical services to assist with daily living and independence); **OR**
- ◆ Services are solely requested for the comfort or convenience of the caregiver or family member versus the medical necessity of the patient.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HC PCS Code	Code Description
G0155	Services of clinical social worker in home health or hospice settings, each 15 minutes
G0162	Skilled services by a registered nurse (RN) for management and evaluation of the plan of care; each 15 minutes (the patient's underlying condition or complication requires an RN to ensure that essential non-skilled care achieves its purpose in the home health or hospice setting)
G0320	Home health services furnished using synchronous telemedicine rendered via a real-time two-way audio and video telecommunications system
G0321	Home health services furnished using synchronous telemedicine rendered via telephone or other real-time interactive audio-only telecommunications system
G0322	The collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency (i.e., remote patient monitoring)
G0493	Skilled services of a registered nurse (RN) for the observation and assessment of the patient's condition, each 15 minutes (the

	change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment in the home health or hospice setting)
G0494	Skilled services of a licensed practical nurse (LPN) for the observation and assessment of the patient's condition, each 15 minutes (the change in the patient's condition requires skilled nursing personnel to identify and evaluate the patient's need for possible modification of treatment in the home health or hospice setting)
G0495	Skilled services of a registered nurse (RN), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes
G0496	Skilled services of a licensed practical nurse (LPN), in the training and/or education of a patient or family member, in the home health or hospice setting, each 15 minutes
S9127	Social work visit, in the home, per diem
G0299	Direct skilled nursing services of a registered nurse (RN) in the home health or hospice setting, each 15 minutes
G0300	Direct skilled nursing services of a licensed practical nurse (LPN) in the home health or hospice setting, each 15 minutes
Q5001	Hospice or home health care provided in patient's home/residence
Q5002	Hospice or home health care provided in assisted living facility
Q5009	Hospice or home health care provided in place not otherwise specified (NOS)

Medical Evidence

A 2022 *JAMA* unblinded randomized controlled trial (RCT) reviewed the outcomes of an intensive home health program on Medicaid-eligible patients. The study included 5,670 Medicaid-eligible nulliparous pregnant individuals under 28 weeks' gestation. Participants were randomized to the intensive home visiting program (n=3806) or usual care (n=1864). Home nursing visits began prenatally and continued for 2 years after birth. Nurses provided in-home assessments and education around prenatal health, child health, and maternal life planning. The primary outcome of adverse birth outcomes (a composite variable comprising preterm birth, low birth weight, small for gestational age, or perinatal mortality) displayed no significant improvement among home health recipients. However, the authors emphasize the fact that, at the time of publication, the remaining primary outcomes (interbirth intervals of less than 21 months and major injury or concern for abuse or neglect in the child's first 24 months), as well as many secondary outcomes relating to long-term maternal and childhood health, had not yet been completed. Hence, the true impact of home visiting services on this population cannot yet be articulated. Importantly, a secondary analysis of this RCT published in December 2024 found a reduction in emergency department utilization in the postpartum period.^{26,27}

In 2021, *JAMA* published a study by Arsenault-Lapierre et al examining the role of home health in reducing the risk of inpatient readmission. This systematic review included 959 patients across 9 RCTs. Patients were community-dwelling, diagnosed with a chronic disease, and received in-home care as an alternative to inpatient treatment. Home health was associated with a 26% reduction, as well as a lower risk of admission to a long-term care (LTC) facility.⁸

A 2024 study evaluated patients discharged from Boston Children's Hospital's neonatal intensive care unit (NICU). The authors included 155 parents of infants discharged from the NICU to a home health setting who completed the "NICU to Nursery" pre-discharge and post-discharge assessment and training program. This qualitative study found that visiting nurses most often educated parents on the management of tubes and drains, growth and nutrition, and response to emergency situations.²⁸

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Clinical Guideline Revision History/Information

Original Date: April 10, 2025		
Review History		



Cohere Medicare Advantage Policy – Respite Care

Clinical Policy for Medical Necessity Review

Version: 2

Policy Number: CHP-068-2

Cohere Health UMC Approval Date: March 26, 2026

Last Annual Review: March 26, 2026

Revision: Not Applicable

Next Annual Review: March 26, 2027

Important Notices

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Policy Information:

Specialty Area: Home Health

Policy Name: Cohere Medicare Advantage Policy - Respite Care

Policy Number: CHP-068-2

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Respite Care

Related Centers for Medicare & Medicaid Services (CMS) Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Cohere defines CMS coverage criteria¹ as follows:

- Fully established: Applicable LCD or NCD is comprehensive and does not require additional criteria to determine medical necessity consistently.
- Not fully established: Additional, unspecified criteria are needed to interpret or supplement general provisions to determine medical necessity consistently. The additional Cohere criteria will provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

For each jurisdiction, Cohere's internal coverage criteria will only be applied when CMS guidance is not fully established and additional guidelines are needed to support consistent and appropriate decision-making.

Cohere Health's position on NCDs or LCDs related to *Cohere Medicare Advantage Policy - Respite Care* is reflected in Table 1 below. For the LCDs that are not fully established, please refer to the far right column as a guide for the application of Cohere Medicare Advantage criteria.

Table 1 – Related CMS Policies (NCDs or LCDs)

Type	Title	Number	Cohere Definition of CMS Policy Establishment	Indications not fully established by CMS policy (refer to Cohere Health MA medical necessity criteria for these topics):
NCD	No NCD available	N/A	N/A	N/A
LCD	No LCD Available for Jurisdiction	N/A	N/A	Use Cohere Medicare Advantage internal coverage criteria

Description

There are two types of respite care service benefits, based on the location of services: In-home or home respite care and inpatient respite care. Medicare covers a limited number of days of inpatient respite care but does not pay for home respite care services.²

This medical policy is for home respite care services. Respite care is a temporary form of caregiving for a person who is unable to live independently. Respite care gives primary caregivers time to rest, recharge, or recover from an illness or surgical procedure. Respite care services in the home offer a familiar environment that may already include adaptive equipment and other modifications needed by the person receiving care.^{2,3}

Medical Necessity Criteria

Indications

Respite care is considered appropriate if **ANY** of the following is **TRUE**:

- This is not applicable, as Medicare does not reimburse for S and T codes.^{A,B,4}

Non-Indications

Respite care is not considered appropriate if **ANY** of the following is **TRUE**:

- This is not applicable, as there are no indications.

Definitions and Notes

^A **S codes** (e.g., S9125) are not payable by Medicare.

^B **T codes** (e.g., T1005) are not payable by Medicare.

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
S9125	Respite care, in the home, per diem
T1005	Respite care services

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.¹

The potential clinical harms of using these criteria for home respite care may include:

- Adverse effects from delayed or denied treatment, such as greater risk of abuse or neglect of children and youth with intellectual or developmental disabilities.⁵
- Caregiver wellbeing. Because respite care is intended to permit the primary caregiver to rest and engage in other activities, noncoverage of this service may affect caregiver wellness.^{2,3,6}
- Increased healthcare costs and complications from the avoidable use of emergency services and additional treatments.

The clinical benefits of using these criteria for home respite care may include:

- Adequate level of care. Patients may receive an appropriate level of care at home without escalating to more expensive skilled nursing.^{2,3,6}
- Appropriate allocation of healthcare resources at the individual beneficiary and population levels.
- Enhanced overall patient satisfaction and healthcare experience.

Medical Evidence

Huynh et al. (2025), in a qualitative study (purposive sampling, semi-structured interviews, surveys, and thematic analysis) of 35 participants (family members, residents, residential staff, and providers), found that temporary inpatient respite often posed hardships for the primary caregiver and the person being cared for. For example, some people with cognitive impairments may experience increased symptoms (e.g., delirium) from the transition to an unfamiliar environment. Providers report challenges of completing a clinical assessment and plan of care for someone receiving very short-term inpatient respite care (e.g., 1 week), especially since up-to-date medical histories may not be readily available for those cared for at home by a family member or friend. This may result in quality-of-care issues, such as medication errors, which may be less likely to occur with home respite care.⁷

In an American Academy of Pediatrics (AAP) report reaffirmed in 2025, the authors discussed respite care as one of the home and community-based services that can provide psychosocial support to families of children and youth with special healthcare needs (CYSHCN). The authors noted siblings of CYSHCN have higher risk of emotional and behavioral problems, and this risk may increase when the child has special healthcare needs of greater complexity.⁵

The National Institute for Health and Care Excellence (NICE) developed a quality standard describing measures to support primary caregivers. Published in 2021, the 4th quality statement in this guideline discusses “breaks” from primary caregiving and endorses the value of respite.⁶

A 2019 prospective, quasi-experimental study of in-home respite care for primary caregivers of people with dementia looked at caregiver burden, with secondary outcomes including the caregiver’s desire to institutionalize the person with dementia. There were 198 dyads composed of a caregiver and the person they were caring for: 99 were in the intervention (home respite care services) group, and 99 were matched controls. Two weeks after receiving respite, caregivers reported significantly lower levels of strain. However, at 6 months’ follow-up, there was no significant difference between

the intervention and control groups' reports of burden. However, at the 6-month mark, the intervention group did report significantly lower desire to institutionalize the person they were caring for.⁸

Multiple authors have concluded that further research is necessary to understand the potential impacts of respite care.⁷⁻¹¹

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Policy Revision History/Information

Original Date: April 03, 2025		
Review History		
Version 2	03/26/2026	Annual review. No changes to medical necessity criteria or procedure codes. Expanded the Medical Evidence section and added 4 new references.



Cohere Medical Policy – Respite Care

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: April 3, 2025

Important Notices

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Guideline Information:

Specialty Area: Home Health

Guideline Name: Cohere Medical Policy - Respite Care

Date of last literature review: 3/27/2025

Document last updated: 4/2/2025

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Respite Care

Recommended Clinical Approach

Respite care is clinically unproven and not medically necessary. Respite care is distinct from skilled nursing in that it is a form of custodial care wherein the patient does not require the attendance of a registered or licensed nurse. The patient is generally medically stable but requires assistance with bathing, dressing, grooming, and household tasks such as cooking and cleaning. Respite care is a temporary form of caregiving for a patient who is unable to live independently, most often due to advanced age. It is intended to allow primary caregivers time to travel, rest, or engage in activities that may not otherwise be compatible with primary caregiving. Respite care is generally short-term and may last hours or weeks, depending on the situation for which it is requested. Respite care often takes place in the home due to the familiarity of the environment for the patient, as well as the fact that the home may already be optimized with any appropriate adaptive equipment and other modifications that the individual patient requires.^{1,2}

Medical Necessity Criteria

Indications

- **Respite care** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ This service is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

- **Respite care** is not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
S9125	Respite care, in the home, per diem

Medical Evidence

Respite care is a form of custodial care wherein a patient without complex medical needs is temporarily cared for by another party beyond their primary caregiver. This is typically done so that the primary caregiver may rest or engage in other activities that are not compatible with primary caregiving. Generally, custodial care assists the individual with day-to-day personal needs instead of medical needs. For this reason, skilled home nursing is a distinct clinical entity that is separate from respite care. Custodial care often involves assistance with dressing, feeding oneself, bathing, toileting, and other personal care. It is care that does not require the continued attention or supervision of a medical professional. For this reason, custodial care – and home respite care – is often provided to an individual by family members or friends.¹⁻³

The National Institute for Health and Care Excellence (NICE) developed a quality standard describing measures to support adult primary caregivers. Published in 2021, the 4th quality statement in this guideline discusses “breaks” from primary caregiving and endorses the value of such respite, as well as the importance of freely discussing the caregiver’s needs with the patient’s medical team. NICE defines caregiving breaks as a spectrum, ranging from the caregiver “making time for themselves during their usual routines” up to formalized replacement care, otherwise known as respite care. NICE further notes that caregiving breaks should meet the caregiver’s individual needs in ways such as duration, timing, frequency, and type of break, as well as the importance of arrangements that are reliable and consistent (i.e. avoiding last-minute changes that may confer additional stress for the caregiver).³

A 2019 study of in-home respite care offered to primary caregivers of people with dementia found no significant difference in caregiver burden at six months post-baseline. Although the study was small, including 99 caregiver-patient dyads, it did not suggest an overwhelming, clear benefit of in-home respite care. It joins the limited available literature in the conclusion that further research is necessary in order to understand the true benefits of respite care.^{4,5,7,8,16}

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Clinical Guideline Revision History/Information

Original Date: April 3, 2025		
Review History		



Cohere Medical Policy – Genetic Testing for Spinal Muscular Atrophy

Clinical Policy for Medical Necessity Review

Version: 2

Policy Number: CHP-102-2

Cohere Health UMC Approval Date: May 07, 2026

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Next Annual Review: May 07, 2027

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Policy Information:

Specialty Area: Laboratory Testing

Policy Name: Cohere Medical Policy - Genetic Testing for Spinal Muscular Atrophy

Policy Number: CHP-102-2

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Genetic Testing for Spinal Muscular Atrophy

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Description

Genetic testing is done to either diagnose spinal muscular atrophy (SMA) or to identify potential carriers to inform family planning. SMA is diagnosed by analyzing blood for mutations or deletions in the survival motor neuron (SMN) genes. Approximately 80% of SMA cases are types I and II. Analysis of a patient's SMN1 gene identifies at least 95% of mutations and deletions (SMA types I, II, and III).¹⁻⁹

Screening can help identify carriers of genetic variants associated with certain conditions. While carrier screening does not identify 100% of individuals with an SMN1 or SMN2 gene mutation, a negative screening result indicates a reduced risk that the potential parent is a carrier for a genetic condition (e.g., SMA).^{10,11}

Medical Necessity Criteria

Indications

Genetic testing for spinal muscular atrophy (SMA) (SMN1 and SMN2) is considered appropriate if **ANY** of the following is **TRUE**^{1,5,6,10}:

- Carrier screening during preconception or pregnancy for one or both reproductive partners^{1-3,6,12}; **OR**
- Newborn screening (NBS)^{1,3,7,10}; **OR**
- Rescreening requested by genetics professional for **ANY** of the following^{2,8}:
 - Evaluation for additional mutations or deletions that were not available during initial screening²; **OR**
 - Lab error produced an incomplete or uninterpretable result; **OR**
- Diagnostic testing for SMA, including **ANY** of the following:
 - Confirmatory or reflex testing (i.e., SMN1/SMN2 copy-number analysis) after positive NBS^{3,7,13-16}; **OR**
 - To determine (FDA-approved) therapy in patients with a diagnosis of SMA; **OR**
 - Preimplantation genetic testing (PGT) of donor genetic material during assisted reproductive technology¹⁻³; **OR**
 - Prenatal testing with **ANY** of the following^{1-3,6,12}:
 - Abnormal findings on fetal ultrasound¹⁷; **OR**
 - Both reproductive partners have an identified disease-causing mutation in the SMN1 gene¹; **OR**

- Mother is a confirmed carrier, and father's status is unknown (e.g., unavailable for testing); **OR**
- Symptoms of SMA¹; **OR**
- Retesting requested by genetics professional for **ANY** of the following^{2,8,18}:
 - Evaluation for additional mutations or deletions that were not available during initial testing²; **OR**
 - Lab error produced an incomplete or uninterpretable result; **OR**
- SMN1 sequencing with **ANY** of the following:
 - High clinical suspicion in infant with negative screen¹⁵; **OR**
 - Noninformative result of SMN1/SMN2 copy number analysis; **OR**
 - Previous test result suggests potential compound heterozygote¹⁵; **OR**
 - SMN1 exon 7 deletion test result did not show homozygous SMN1 deletion.¹⁹

Non-Indications

Genetic testing for spinal muscular atrophy (SMA) (SMN1 and SMN2 genes) is not considered appropriate if **ANY** of the following is **TRUE**:

- Repeat screening or testing (beyond a scenario outlined above).^{2,10}

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0236U	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (e.g., spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions
81329	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; dosage/deletion analysis (e.g., carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed
81336	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; full gene sequence
81337	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; known familial sequence variant(s)

Medical Evidence

In a controlled trial, Schwartz et al. (2024) compared the effectiveness of newborn screening (NBS) for spinal muscular atrophy (SMA) with screening after the onset of SMA symptoms. There were 234 participants (n=44 in the newborn cohort; n=190 in the clinical symptom-onset cohort) with genetically confirmed SMA and up to three SMN2 copies were included in the trial. Children with more than three SMN2 copies typically experience onset of clinical symptoms at a later age. The mean age at the start of treatment with a disease-modifying drug was 1.3 months in the newborns and 10.7 months in the clinical symptom-onset cohort. After treatment, 40 of 44 newborns (90.9%) were able to sit unsupported compared to 141 of 190 (74.2%) in the clinical symptom-onset cohort. Those screened at birth were four times as likely to walk independently (63.6% vs. 14.7%). Compared with infants who were screened and treated after clinical symptoms appeared, the newborn cohort had better treatment response and improved functional outcomes (e.g., significantly less likely to need feeding tubes or ventilator support). Overall, the trial demonstrated the effectiveness of newborn screening for SMA in enabling earlier intervention.¹³

Keinath et al. (2021) reviewed the clinical relevance of testing for spinal muscular atrophy (SMA). Strong evidence supports screening to identify couples in which one or both partners are carriers. Screening enables a couple to make informed decisions about reproductive choices as well as treatment decisions once a child with SMA is born. Early detection improves outcomes of newborns who start treatment before motor neuron loss.³

Mercuri et al. (2018) provided recommendations for diagnosing and managing SMA. Topics included genetics, organs affected, physical therapy and rehabilitation, specialty care (e.g., pulmonology), and prescriptions. The standard for genetic testing was reported as “a quantitative analysis of both SMN1 and SMN2 using multiplex ligation-dependent probe amplification (MLPA), quantitative polymerase chain reaction (qPCR) or next generation sequencing (NGS).”⁹

The American College of Obstetricians and Gynecologists (ACOG) published two committee opinions on carrier screening. For spinal muscular atrophy (SMA) specifically, ACOG recommends offering screening to those already pregnant and those considering pregnancy. This is because the gene mutation that causes SMA is relatively common, and SMA is the leading genetic cause of death in infants. However, in their guidelines, ACOG recommends carrier screening for cystic fibrosis, thalassemias, and hemoglobinopathies, along with SMA screening. ACOG states that, ideally, carrier screening is offered before conception, because this allows a family to decide whether to conceive or use advanced reproductive technologies (e.g., donor gametes). In a committee opinion reaffirmed in 2025, ACOG recommended a carrier screening panel of 20 conditions based on consensus-determined criteria.^{2,10}

The American College of Medical Genetics and Genomics (ACMG), in a 2021 practice resource, recommends offering Tier 3 carrier screening to all pregnant patients and those planning a pregnancy. Tier 3 screening includes heritable conditions with a carrier frequency greater than or equal to 1/200.¹²

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Policy Revision History/Information

Original Date: December 8, 2023		
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Version 2	05/07/2026	Annual review. Added indications for newborn screening, testing individuals with SMA symptoms, rescreening, and sequencing. Removed criteria for genetic counseling. Added non-indication for repeat screenings. Updated terminology from “screening during reproductive assistance” to “preimplantation genetic testing.” No changes to procedure codes. Expanded the Medical Evidence section and added 10 references; updated ACOG opinions and <i>GeneReviews</i>. Removed NINDS lay website reference.



Cohere Medical Policy – Laparoscopic Gynecologic Surgery

Clinical Policy for Medical Necessity Review

Version: 2

Policy Number: CHP-057-2

Cohere Health UMC Approval Dates: March 10, 2026

Last Annual Review: March 10, 2026

Revision: Not Applicable

Next Annual Review: March 10, 2027

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Policy Information:

Specialty Area: Obstetrics and Gynecology

Policy Name: Cohere Medical Policy - Laparoscopic Gynecologic Surgery

Policy Number: CHP-057-2

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Laparoscopic Gynecologic Surgery

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity.

Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
 - The medical necessity of each individual request
 - Why prior imaging or procedures were inconclusive, or why additional/follow-up studies are needed
 - How the results will impact patient management or treatment decisions
- Duplicate exams or requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the patient's primary symptoms can be adequately assessed and/or treated with a single study or procedure.

Description

Laparoscopic gynecologic surgery is performed to diagnose and treat conditions such as fibroids, endometriosis, pelvic pain, ovarian cysts, and ectopic pregnancy. The procedure involves a laparoscope which is attached to a camera. Procedures include ovarian cyst removal, fibroid removal, endometrial tissue ablation, removal of pelvic adhesions, tubal ligation, Burch procedure, vault suspension, ectopic pregnancy removal, as well as urethral and vaginal reconstruction surgery.^{1,2}

Medical Necessity Criteria

Indications

Laparoscopic gynecologic surgery is considered appropriate if **ANY** of the following is **TRUE**²⁻⁴:

- Neoplastic conditions including **ANY** of the following:
 - Ovarian cancer with **ANY** of the following⁵:
 - Laparoscopic resection; **OR**
 - Early-stage/low-risk disease and patient desires future fertility; **OR**
 - Relapsed malignant sex cord-stromal tumor; **OR**
 - Ovarian carcinoma and cytoreductive surgery and **ALL** of the following:
 - Absence of ascites; **AND**
 - Limited foci of disease amenable to complete resection; **AND**
 - Good/acceptable performance status (e.g., able to complete activities of daily living)^{65,66}; **AND**
 - Recurrence of at least six months following chemotherapy treatment with a complete response; **OR**
 - Uterine sarcoma with **ANY** of the following⁶:
 - Isolated pelvic residual disease or recurrence; **OR**
 - Isolated vaginal residual disease or recurrence; **OR**
- **ANY** of the following related to treatment or evaluation of infertility^{7,8}:
 - Evaluation or treatment of infertility or recurrent pregnancy loss with **ALL** of the following:
 - Evidence of infertility as indicated by **ANY** of the following:
 - Less than 35 years of age and unable to conceive following 1 year or more of unprotected sexual intercourse⁷; **OR**

- Greater than or equal to 35 years of age and unable to conceive following 6 months or more of unprotected sexual intercourse⁷; **OR**
- Two or more consecutive spontaneous abortions⁹; **AND**
- Hormone laboratory results (e.g., prolactin, follicle-stimulating hormone, mid-luteal progesterone) indicate normal endocrine function; **AND**
- Imaging (e.g., transvaginal ultrasound, hysterosalpingogram, sonohysterography) is **ANY** of the following:
 - Non-diagnostic; **OR**
 - Shows pathology that can be managed surgically (e.g., endometriosis); **OR**
- Polycystic ovary syndrome (PCOS) that has not responded to pharmacological treatment (e.g., letrozole, clomiphene citrate, metformin) for at least one cycle^{10,11}; **OR**
- Myomectomy for **ANY** of the following¹²⁻¹⁶:
 - Acute torsion of pedunculated leiomyoma (fibroids); **OR**
 - Leiomyoma and **ALL** of the following:
 - Symptoms include **ANY** of the following:
 - Abnormal uterine bleeding (AUB)^A; **OR**
 - Dyspareunia; **OR**
 - Infertility; **OR**
 - Iron-deficiency anemia; **OR**
 - Pelvic pain or pressure; **OR**
 - Urinary or bowel dysfunction; **AND**
 - Symptoms not responsive to medical management (e.g., hormonal therapy, NSAIDs) as indicated by **ANY** of the following:
 - Medical management trialed for greater than or equal to 3 months; **OR**
 - Medical management contraindicated or not tolerated; **OR**
- Oophorectomy (removal of ovary) with **ANY** of the following:
 - Adjuvant or risk-reducing treatment in a patient with **ALL** of the following:
 - Greater than or equal to 18 years of age; **AND**
 - Bilateral salpingo-oophorectomy for **ANY** of the following:
 - Documentation of cancer susceptibility gene (e.g., BRCA1, BRCA2, BRIP1, RAD51C, RAD51D)¹⁹⁻²¹; **OR**

- Familial cancer syndrome associated with an elevated risk of ovarian cancer (e.g., hereditary nonpolyposis colorectal cancer [HNPCC], Lynch syndrome)²²⁻²⁴; **OR**
 - Premenopausal patient with estrogen or progesterone receptor-positive breast cancer^{17,18}; **OR**
 - Strong family history (one or more first-degree relatives) of ovarian or early-onset breast cancer²⁵; **OR**
- Adnexal mass or ovarian disease²⁶⁻²⁸; **OR**
- Adnexal torsion^{26,29,30}; **OR**
- Androgen-producing ovary unresponsive to medical therapy; **OR**
- Severe premenstrual syndrome/premenstrual dysphoric disorder symptoms in a patient greater than or equal to 18 years of age with **ANY** of the following^{31,32}:
 - Failure of medical therapy (e.g., diuretics, hormone therapies, selective serotonin re-uptake inhibitors); **OR**
 - Medical therapy produces unacceptable side effects; **OR**
- As part of gender-affirming care with **ALL** of the following³³⁻³⁵:
 - Greater than or equal to 18 years of age; **AND**
 - Signed letter from a qualified mental health professional attesting to **ALL** of the following:
 - Ability to provide fully informed consent; **AND**
 - Diagnosis of gender dysphoria; **AND**
 - Readiness for surgical treatment; **AND**
 - Greater than or equal to 6 months of continuous hormone therapy; **AND**
 - Any significant physical or mental health concerns are well-controlled; **OR**
- Oophoropexy (ovarian transposition) in a premenopausal patient with **ANY** of the following:
 - Pelvic irradiation for cancer³⁶; **OR**
 - Adnexal torsion with **ANY** of the following^{28,30,37-39}:
 - Absent contralateral ovary; **OR**
 - Anatomical or congenital high-risk of torsion; **OR**
 - Repeat torsion; **OR**
- Salpingectomy (removal of the tube) with **ANY** of the following:
 - Adnexal cyst with tubal involvement⁴⁰; **OR**
 - Adnexal torsion^{29,41,42}; **OR**
 - Hydrosalpinx^{36,42,43}; **OR**

- Tubal sterilization in a patient greater than or equal to 18 years of age^{36,44}; **OR**
- As opportunistic ovarian cancer risk reduction when performed during pelvic surgery^{45,46}; **OR**
- Chronic pelvic pain with **ALL** of the following⁴⁷⁻⁴⁹:
 - Pain lasting greater than or equal to three months; **AND**
 - Physical examination and medical history (e.g., pelvic and abdominal examination, laboratory tests, imaging) non diagnostic; **AND**
 - **ANY** of the following:
 - Pain interferes with the patient's function and mobility; **OR**
 - Concern about interference with other chronic pain treatments; **OR**
- Endometrioma⁵⁰⁻⁵²; **OR**
- Endometriosis is suspected, with **ALL** of the following^{48,50,51,53}:
 - Moderate to severe pain that is not treatable with NSAIDs; **AND**
 - Other etiology of pain is not identified by history, physical examination, and testing (e.g., transvaginal ultrasound); **AND**
 - Prescribed hormone therapy is unsuccessful or not appropriate and **ANY** of the following:
 - Failure of an observed trial of hormone therapy for 3 months or more (e.g., oral contraceptive pills, levonorgestrel intrauterine system, estrogen/progestin, gonadotropin-releasing hormone analogs); **OR**
 - Patient wishes to preserve fertility and medical treatments are not appropriate; **OR**
 - Side effects of treatment are intolerable; **OR**
- Ectopic pregnancy with anatomy or pathology preventing routine ectopic removal⁵⁴; **OR**
- Any process within the pelvic region (e.g., adhesion, neoplasm, endometriosis) that interferes with the normal function of pelvic organs (e.g., ureter, bowel).^{48,55-58}

Non-Indications

- There are no absolute non-indications for laparoscopic gynecologic surgery.⁵⁹

Definitions and Notes

^A**Abnormal uterine bleeding (AUB):** Uterine bleeding that is abnormal in volume, duration, frequency, or regularity, occurring in the absence of pregnancy. AUB includes, but is not limited to, heavy menstrual bleeding/excessive blood loss (menorrhagia), intermenstrual bleeding (metrorrhagia), bleeding more often than every 21 days (polymenorrhea), and bleeding less often than every 35 days (oligomenorrhea).^{60,61}

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas
58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58662	Laparoscopy, surgical; with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface by any method
58670	Laparoscopy, surgical; with fulguration of oviducts (with or without transection)

Medical Evidence

Tozzi et al. (2024) conducted a non-randomized prospective clinical trial (ULTRA-LAP) to determine the safety and efficacy of laparoscopic Visceral-Peritoneal Debulking (L-VPD) for patients with stage III-IV ovarian cancer (OC). An initial pilot study identified 208 patients for the ULTRA-LAP TRIAL who underwent exploratory laparoscopy followed by L-VPD. The authors concluded that exploratory laparoscopy identified patients to demonstrate the efficacy of L-VPD. While it is practical and achievable for patients with OC, further research is warranted to ensure successful patient outcomes. (ClinicalTrials.gov Identifier: NCT05862740).⁶²

Laughlin-Tommaso et al. (2020) reported a comparative study on short-term health-related quality of life (QoL) outcomes following myomectomy. A national registry was used to identify pre-menopausal patients scheduled for hysteroscopic, abdominal, or laparoscopic myomectomy. Of the 1206 patients included, all reported improved QoL. The authors noted that laparoscopic and abdominal techniques have a faster recovery time.⁶³

Eleje et al. (2018) analyzed ten cohort studies including 8087 participants to determine the benefits of risk-reducing salpingo-oophorectomy (RRSO) in women with BRCA1 or BRCA2 mutations. Overall survival was longer than in patients without RRSO. The authors noted that future research should focus on bone fracture incidence, QoL, or severe adverse events for RRSO.⁶⁴

Rieger et al. (2015) conducted a single-institution retrospective chart review of gynecologic laparoscopic surgery in patients under 21 years of age, evaluating patient demographics, surgical indications, and surgical outcomes. Their final analysis included 158 patients: 33 premenarcheal (mean age 8.6 years) and 125 menarcheal (mean age 14.7 years). They reported that acute abdominal pain was the most common presenting condition in both menarcheal and premenarcheal patients. Other surgical indications included chronic pelvic pain, congenital anomaly, and pelvic mass on diagnostic imaging. Reported surgical procedures included those to adnexal structures, uterine procedures, peritoneal procedures, and gastrointestinal procedures, with the authors reporting 17 specific procedures. Specific procedures

included adnexal cystectomy, cyst drainage, adnexal detorsion, oophorectomy, ovarian debulking, salpingectomy, excision of uterine mass, lysis of adhesions, and appendectomy, with adnexal cystectomy being the most commonly reported procedure. Outcomes were generally good, with no complications reported in premenarcheal patients and 2 minor complications in menarcheal patients. The authors concluded that laparoscopic gynecological procedures are safe and well-tolerated in pediatric patients.³

Batchelor and Shim (2025) reviewed the literature on the evaluation and surgical treatment of gynecologic pelvic pain in pediatric patients. They noted that the evaluation should include a physical examination and detailed history, followed by imaging and laboratory testing as appropriate. They reported that, among pediatric patients, endometriosis is the most common cause of secondary dysmenorrhea. First-line therapy for endometriosis includes medical management with hormonal contraceptives, progestin-only therapies, and gonadotropin-releasing hormone analogs for select patients. Persistent pain despite 3–6 months of treatment with first-line medications may indicate the need for diagnostic and therapeutic laparoscopic surgery. The authors recommended that surgeons performing diagnostic laparoscopy be familiar with the surgical management of endometriosis in order to prevent repeat surgeries. Surgical management techniques may include excision or ablation of the lesions.⁴⁸

The American College of Obstetricians and Gynecologists (ACOG) has issued several committee opinions and practice bulletins relevant to laparoscopic gynecologic surgeries. The 2019 committee opinion on opportunistic salpingectomy as a strategy for prevention of epithelial ovarian cancer notes that removing a patient's fallopian tubes at the same time as the primary pelvic procedure (e.g., hysterectomy) may decrease the patient's risk of later developing ovarian cancer. The committee notes strong molecular and gene expression evidence that many ovarian cancers originate in the fallopian tubes. Additionally, the opinion cites a Swedish study that reported a 65% reduction in the risk of ovarian cancer in women who had undergone a salpingectomy. Notably, peri- and post-surgical complications, including blood transfusions, readmissions, and infections, are not increased when salpingectomy is done along with hysterectomy.⁴⁵ A 2013 Society of

Gynecologic Oncology (SGO) clinical practice statement salpingectomy for ovarian cancer prevention, similarly recommends salpingectomy at the time of hysterectomy and other pelvic surgery in patients who do not desire future fertility.⁴⁶

The 2020 (reaffirmed in 2026) ACOG practice bulletin on chronic pelvic pain notes that diagnostic laparoscopy may be included in the diagnostic process when there is suspicion of chronic pelvic inflammatory disease.⁶⁴ The 2021 (reaffirmed in 2025) ACOG practice bulletin on the management of symptomatic uterine leiomyomas notes that surgical treatment options for uterine leiomyomas include laparoscopic myomectomy. Specifically, laparoscopic myomectomy is appropriate for patients who desire future fertility and who have symptomatic type 2 through type 8 leiomyomas. The bulletin notes that, compared to abdominal myomectomy, laparoscopic myomectomy is associated with faster return to work and normal activities, less postoperative pain, shorter hospitalization, and a lower risk of postoperative fever.¹²

The 2016 (reaffirmed in 2025) ACOG practice bulletin on the evaluation and management of adnexal masses notes that minimally invasive procedures, including laparoscopy, are preferred for presumed benign masses. The bulletin notes that several retrospective studies have demonstrated outcomes similar to those of laparotomy, with lower complication rates and faster recovery times after laparoscopy. The bulletin further notes that while less common, adnexal masses may be present in pediatric and adolescent patients. Surgical management of benign masses in pediatric patients should aim to preserve fertility and may include unilateral salpingo-oophorectomy by laparoscopy.⁶⁵ The 2019 (reaffirmed in 2021) ACOG committee opinion on adnexal torsion in adolescents notes that diagnostic laparoscopy is indicated when adnexal torsion is suspected due to intermittent, non-radiating abdominal pain. Adnexal torsion can only be surgically diagnosed. When adnexal torsion is confirmed, the committee recommends a minimally invasive approach that includes detorsion and preservation of the adnexal structures. Routine oophorectomy is not recommended, and removal of a torsed ovary should only proceed when unavoidable (e.g., severely necrotic ovary).³⁰

The 2019 American Society for Reproductive Medicine (ASRM) committee opinion on postoperative adhesions in gynecologic surgery notes that infertility, pain, and bowel obstruction may result from postsurgical tissue trauma and healing. Surgical record analyses have noted that approximately one third of abdominal or pelvic surgical patients were readmitted within 10 years for conditions related to adhesions, with 20% of these within the first year.⁵⁸

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Policy Revision History/Information

Original Date: December 08, 2023		
Review History		
Version 2	03/10/2026	Annual review. Policy title changed to better reflect codes and criteria. Now titled "Laparoscopic gynecologic surgery". Formerly titled "Exploratory laparoscopic gynecologic surgery". Removed the following criteria (not relevant to codes): Treatment and evaluation of cervical cancer, endometrial cancer; cytoreduction for primary peritoneal cancer, fallopian tube cancer, ovarian cancer; salpingectomy for tubo-ovarian abscess; transabdominal cerclage. Added recurrent pregnancy loss to infertility indications. Added the following indications for oophorectomy in a patient greater than 18 years of age: treatment of severe premenstrual syndrome, gender affirming care. Added requirement that patient is greater than 18 years of age for the following: Adjuvant or risk-reducing oophorectomy, salpingectomy for tubal sterilization

		Added indications for oophoropexy for the treatment of adnexal torsion. Added indication for salpingectomy for opportunistic ovarian cancer risk reduction when performed during pelvic surgery. Editorial and stylistic changes to criteria improve accuracy, clarity, and usability. Added definition for abnormal uterine bleeding. Updated all medical society guidelines (e.g., NCCN, ACOG, ACR) to most recently available. Updated medical evidence section: Review of select literature on pediatric patients and select medical society guidelines.



Cohere Medicare Advantage Policy – Esophagogastroduodenoscopy (EGD)

Clinical Guidelines for Medical Necessity Review

Version: 2.1

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Important Notices

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Guideline Information:

Specialty Area: Gastroenterology

Guideline Name: Cohere Medicare Advantage Policy - Esophagogastroduodenoscopy (EGD)

Type: ☒ Adult (18+ yo) | ☒ Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Esophagogastroduodenoscopy (EGD)

Related CMS Documents

Please refer to the [CMS Medicare Coverage Database](#) for the most current applicable CMS National Coverage.⁵⁴⁻⁶⁰

- [National Coverage Determination \(NCD\) Endoscopy \(100.2\)](#)
- [Local Coverage Determination \(LCD\). Diagnostic and therapeutic esophagogastroduodenoscopy \(L33583\)](#)
 - [Billing and Coding: Diagnostic and therapeutic esophagogastroduodenoscopy \(A57063\)](#)
- [Local Coverage Determination \(LCD\). Upper gastrointestinal endoscopy \(diagnostic and therapeutic\) \(L35350\)](#)
 - [Billing and Coding: Upper gastrointestinal endoscopy \(diagnostic and therapeutic\) \(A57414\)](#)
- [Local Coverage Determination \(LCD\). Upper gastrointestinal endoscopy and visualization \(L34434\)](#)
 - [Billing and Coding: Upper gastrointestinal endoscopy and visualization \(A56389\)](#)

Description

Esophagogastroduodenoscopy (EGD) is an upper intestinal endoscopy technique used to examine, obtain samples, or treat pathological conditions of the upper intestinal tract. EGD is performed with a lighted, flexible, fiberoptic instrument, usually less than 12 mm in diameter, passed through the cricopharynx. The patient receives conscious sedation, and a topical anesthetic may be applied to the posterior pharynx. The entire esophagus, stomach, and duodenum can be visualized with EGD. Endoscopic ultrasound (EUS) or transendoscopic ultrasound uses a transducer at the end of an endoscope to obtain high-resolution images that improve visualization of the gastrointestinal tract and allow evaluation of adjacent structures, including the pancreas and biliary tree.

Diagnostic EGD is used to visualize the oropharynx, esophagus, stomach, and proximal duodenum and is useful for detecting conditions such as focal benign or malignant lesions, diffuse mucosal changes, luminal obstruction, abnormal motility, and extrinsic compression by contiguous structures.⁵ A diagnostic EGD allows the examiner to visualize abnormalities detectable by the technique and to photograph and collect a biopsy sample as appropriate. An endoscopic Doppler probe can be used as an adjunct diagnostic modality to assess local blood supply and efficacy of treatment and to stratify patients at higher risk of repeat upper gastrointestinal bleeding (UGIB). Pulsatile Doppler signals can indicate the presence and path of bleeding vessels. The probe can also determine if vessels were appropriately coagulated following endoscopic hemostasis. The absence of a Doppler signal is consistent with successful hemostasis of a bleeding lesion. Lesions with a persistent Dopplerable signal have a higher risk for rebleeding.⁶

EGD is generally considered a safe procedure, although bleeding, perforation, infection, acute pancreatitis,⁷ and sedation-related complications⁸ following the procedure have been reported in rare instances.⁹

Medical Necessity Criteria

Indications

Esophagogastroduodenoscopy (EGD) is considered appropriate if **ANY** of the following is **TRUE**^{55,57,59-60}:

- Gastroesophageal reflux disease (GERD) symptoms (e.g., heartburn, regurgitation, or chest pain) that persist despite treatment⁵⁻⁶; **OR**
- A single screening exam for GERD with **AT LEAST THREE** of the following risk factors for concurrent Barrett's esophagus¹⁵:
 - Prolonged GERD for more than 5 years; **OR**
 - The age of the patient is greater than 50 years; **OR**
 - Male gender; **OR**
 - Hiatal hernia⁷⁻⁸; **OR**
 - Current or past tobacco use; **OR**
 - Obesity; **OR**
 - Family history of Barrett's esophagus in a first-degree relative; **OR**
 - Family history of esophageal adenocarcinoma in a first-degree relative; **OR**
- Planning for anti-reflux surgery⁹; **OR**

- Nausea that is persistent and unexplained⁶; **OR**
- Vomiting that is persistent and unexplained⁵⁻⁶; **OR**
- Atypical chest pain after cardiac disease has been ruled out⁶; **OR**
- Heartburn with alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss)^{8,10}; **OR**
- Prolonged anorexia⁵; **OR**
- Unexplained weight loss⁵; **OR**
- Effects of nonsteroidal anti-inflammatory drug (NSAID) use¹¹; **OR**
- Barrett's esophagus is present, and the patient requires **ANY** of the following¹²:
 - Routine surveillance of non-dysplastic disease every 1 to 5 years^{1,13}; **OR**
 - Reassessment during treatment to eliminate dysplasia (e.g., ablation, mucosal resection, mucosal dissection) every 3 to 6 months¹²; **OR**
 - Surveillance after completion of treatment for dysplasia when **ANY** of the following is **TRUE**¹:
 - For low-grade dysplasia – initially at 2–3 months after diagnosis, and then, if persistent, every 6 months for 1 year, then annually thereafter^{55,57,59-60}; **OR**
 - For high-grade dysplasia – every 3 months for 1 year, then every 6 months for 1 year, then annually thereafter; **OR**
- Swallowing symptoms including, but not limited to, **ANY** of the following^{55,57,59-60}:
 - Difficulty swallowing (e.g., dysphagia); **OR**
 - Pain while swallowing (odynophagia); **OR**
- Esophageal dysmotility based on barium radiography or esophageal manometry, when suggestive of achalasia¹⁴; **OR**
- Confirmation and specific histologic diagnosis of radiologically demonstrated lesions, including, but not limited to, **ANY** of the following¹⁴⁻¹⁷:
 - Protrusions/growths from, within, or extrinsic to the mucosal wall; **OR**
 - Excavated lesions, such as erosions, ulcers, or diverticula; **OR**
 - Other mucosal abnormalities, including thickened fold(s) or asymmetric/symmetric narrowing(s) (stenoses/strictures); **OR**
 - Any lesion that requires biopsy for diagnosis;^{55,57,59-60} **OR**
- Clarification of location or pathology of a lesion during surgery¹⁸; **OR**
- Evaluation for possible gastric or duodenal polyps in patients with familial adenomatous polyposis or other at-risk hereditary syndromes (e.g., Lynch syndrome, juvenile polyposis syndrome, Peutz-Jegher's syndrome,

MUTYH-Associated Polyposis [MAP], Li-Fraumeni syndrome, Cowden syndrome, hereditary gastric cancer syndrome)¹⁹; **OR**

- The patient is less than 60 years of age and has dyspepsia with **ANY** of the following:
 - Negative *Helicobacter pylori* test and no response to proton pump inhibitor (PPI) therapy^{6,20-21}; **OR**
 - Equivocal results from non-invasive *Helicobacter pylori* testing and need for gastric biopsy²¹⁻²²; **OR**
 - A one-time screening in a patient with a family history of upper GI malignancy in a first-degree relative; **OR**
 - Lymphadenopathy (e.g., supraclavicular, periumbilical); **OR**
 - Palpable abdominal mass; **OR**
 - Alarm symptoms (e.g., anemia, GI bleeding, unexplained weight loss, dysphagia/odynophagia); **OR**
- The patient is 60 years of age or older and has dyspepsia; **OR**
- Peptic ulcer disease with **ANY** of the following²³⁻²⁴:
 - Persistent or recurrent symptoms despite treatment; **OR**
 - For follow-up of esophageal, gastric or stomal ulcers to demonstrate healing (frequency of follow-up EGDs is variable, but every two to four months until healing is demonstrated is reasonable);^{55,57,59-60} **OR**
 - Follow-up of duodenal ulcer or other lesions of the upper gastrointestinal tract that have resulted in serious consequences (e.g., hemorrhage)^{55,57,59-60}; **OR**
- Erosive reflux esophagitis with **ANY** of the following^{2,23}:
 - Persistent or recurrent symptoms despite appropriate GERD treatment; **OR**
 - To document healing after treatment of LA grade C or D esophagitis and to exclude the development of Barrett's esophagus; **OR**
- Surveillance as determined by the endoscopist for or suspected recurrence of prior upper GI cancer or pre-cancer, including **ANY** of the following²³:
 - Squamous cell carcinoma of the esophagus; **OR**
 - Adenocarcinoma of the esophagus; **OR**
 - Adenocarcinoma or mucosa-associated lymphoma (MALT) of the stomach; **OR**
 - Adenocarcinoma of duodenum or ampulla; **OR**
 - Stromal/neuroendocrine tumor of the esophagus, stomach, or duodenum; **OR**

- Other subepithelial pre-malignant lesion of the esophagus, stomach, or duodenum; **OR**
- Adenomatous polyp of stomach, duodenum, or ampulla; **OR**
- Dysplasia (low or high grade) in patients with gastric intestinal metaplasia or chronic atrophic gastritis; **OR**
- Confirmed or suspected eosinophilic esophagitis (EoE) for **ANY** of the following²⁵:
 - Initial exam for suspected EoE for evaluation of dysphagia, GERD symptoms refractory to PPI therapy, or history of esophageal food bolus impaction; **OR**
 - Follow-up exam to reassess esophageal histology for confirmed EoE, after treatment (e.g., food allergen restriction, PPI therapy, steroid therapy, anti-interleukin therapy); **OR**
 - Follow-up exam to reassess esophagus when symptoms recur on previously effective therapy; **OR**
- Evaluation of chronic diarrhea to identify an upper GI etiology when small bowel disease is suspected^{55,57,59-60}; **OR**
- Suspected celiac disease based on **ANY** of the following²⁶:
 - Typical signs or symptoms (e.g., abdominal pain, diarrhea, constipation, weight loss without intent, iron deficiency anemia); **OR**
 - Abnormal celiac serology including **ANY** of the following:
 - Elevated tissue transglutaminase immunoglobulin A (TTG IgA) with normal total IgA; **OR**
 - Elevated endomysial IgA with normal total IgA; **OR**
 - Elevated deamidated anti-gliadin IgG with IgA deficiency; **OR**
 - The patient is at a high-risk based on celiac human leucocyte antigen (HLA) analysis; **OR**
- Known celiac disease with **ANY** of the following²⁶:
 - The patient has been on a gluten-free diet for at least 1 year and requires histologic confirmation of remission; **OR**
 - Symptoms persist despite adherence to a gluten-free diet for at least 6 months; **OR**
- Acute injury including, but not limited to, **ANY** of the following:
 - Caustic agent ingested^{55,57,59-60}; **OR**
 - Foreign object ingested²⁷; **OR**
- Evaluation for esophagogastric varices (swollen veins [varices] in the esophageal or gastric wall) due to suspicion for or confirmation of liver cirrhosis or portal hypertension²⁸; **OR**

- Routine screening (every 3 years) or surveillance (every 1-2 years) of non-bleeding esophagogastric varices²⁸⁻²⁹; **OR**
- Evaluation of GI bleeding and **ANY** of the following^{55,57,59-60}:
 - Upper GI symptoms; **OR**
 - Presumed chronic blood loss (iron deficiency anemia, positive fecal occult blood test, or both) when investigation of colon is negative³⁰; **OR**
 - Active bleeding is present (hematemesis, melena, or hematochezia); **OR**
 - Recent active bleeding; **OR**
 - Suspected aorto-enteric fistula; **OR**
 - Suspected portal hypertension; **OR**
 - Rebleeding occurs after acute self-limited blood loss; **OR**
 - Rebleeding occurs after recent endoscopic therapy; **OR**
 - Surgery is being considered; **OR**
- Suspected inflammation of the upper gastrointestinal (GI) tract from etiologies including, but not limited to, inflammatory myositis, Crohn's disease, ulcerative colitis, inflammatory bowel disease (IBD), and acute graft versus host disease³¹⁻³²; **OR**
- Conditions in which upper GI pathology might modify other planned management, such as patients with **ANY** of the following⁵:
 - Organ transplantation is planned; **OR**
 - Long-term anticoagulation therapy; **OR**
 - Long-term nonsteroidal anti-inflammatory drug therapy for arthritis; **OR**
 - Cancer of the head and neck; **OR**
 - Bariatric surgery is planned³³; **OR**
- When sampling of duodenal or jejunal tissue or fluid is indicated^{55,57,59-60}; **OR**
- Therapeutic treatment of **ANY** of the following^{55,57,59-60}:
 - Treatment of bleeding from lesions; **OR**
 - Sclerotherapy and/or band ligation for bleeding from esophageal or gastric varices; **OR**
 - Removal of selected polypoid lesions; **OR**
 - Dilatation of strictures in the upper intestinal tract; **OR**
 - Palliative therapy of stenosing neoplasms; **OR**
 - Endoscopic therapy of intestinal metaplasia; **OR**
 - Management of operative complications (e.g., dilatation of anastomotic strictures, stenting of anastomotic disruption, fistula, or leak in selected circumstances); **OR**
- Serial follow-up of **ANY** of the following:^{55,57,59-60}

- Follow-up and treatment of patients with esophageal varices or bleeding lesions requiring recurrent therapy; **OR**
- Follow-up and treatment of esophageal strictures requiring guidewire dilation; **OR**
- Follow-up for removal of percutaneous gastrostomy tube (PEG); **OR**
- **EGD with endoscopic ultrasound** is considered appropriate for **ANY** of the following [55,57,59-60](#):
 - Staging tumors of the GI tract, pancreas, and bile ducts; **OR**
 - Evaluating abnormalities of the GI tract wall or adjacent structures; **OR**
 - Tissue sampling of lesions within, or adjacent to, the wall of the GI tract; **OR**
 - Evaluation of abnormalities of the pancreas, including masses, pseudocysts and chronic pancreatitis; **OR**
 - Evaluation of abnormalities of the biliary tree; **OR**
 - Providing endoscopic therapy of the GI tract under ultrasonographic guidance; **OR**
 - Staging of tumors shown to be metastatic only when the results are the basis for therapeutic decision; **OR**
 - Providing access into the bile ducts or pancreatic duct, either independently or as an adjunct to ERCP; **OR**
 - For transmural injection of therapeutic agents (e.g., ethanol, phenol) including **ANY** of the following:
 - Neurolytic agent (e.g., botulinum toxin, ethanol, phenol) into the celiac plexus for **ANY** of the following:
 - Palliate chronic pain related to upper abdominal cancer (including pancreatic cancer); **OR**
 - Relieve chronic pain related to chronic pancreatitis that is unresponsive to medical therapy; **OR**
 - Identify/predict surgical success in patients with median arcuate ligament syndrome (MALS); **OR**
 - Botulinum toxin into the esophageal muscularis for treatment of achalasia; **OR**
 - For transmural delivery of targeted cancer treatment (eg radiofrequency ablation, chemotherapy); **OR**
 - For transmural placement of fiducial markers in tumors for surveillance or presurgical marking.

Non-Indications

Diagnostic esophagogastroduodenoscopy (EGD) is not considered appropriate if **ANY** of the following is **TRUE**^{55,57,59-60}:

- Blockage in the esophagus, stomach, or duodenum is previously established; **OR**
- Surveillance of healed, benign disease, such as gastric or duodenal ulcer or benign esophageal strictures¹; **OR**
- Confirming *Helicobacter pylori* eradication; **OR**
- Cancer surveillance in patients with pernicious anemia, treated achalasia, or prior gastric resection¹; **OR**
- Patients with significant cardiac arrhythmia or recent (within the last 3-6 months) myocardial infarction¹; **OR**
- Perforated bowel; **OR**
- Peritonitis; **OR**
- Toxic megacolon in an unstable patient; **OR**
- Perforated viscus is known or suspected; **OR**
- Before bariatric surgery in asymptomatic individuals; **OR**
- Confirming placement of gastric band; **OR**
- Diagnosing laryngopharyngeal reflux; **OR**
- Optical endomicroscopy is requested.

***Note:** Patients undergoing dilations, percutaneous endoscopic gastrostomy [PEG], polypectomy, endoscopic sphincterotomy, endoscopic ultrasound-guided fine-needle aspiration [FNA], laser ablation, and coagulation are at higher risk for bleeding, and adjustment of anticoagulation may be necessary.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)

43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43252	Esophagogastroduodenoscopy, flexible, transoral; with optical endomicroscopy
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis.

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of esophagogastroduodenoscopy. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Cardiopulmonary-related adverse events account for over 60% of unplanned events during endoscopy.¹⁰
- Sore throat¹⁰
- Bleeding¹⁰
- Perforation (less than 1 in 2,500 cases)
- Infection due to translocation of endogenous bacterial flora (including *Escherichia coli*, *Klebsiella*, other *Enterobacteriaceae*, and enterococci) from one patient to another¹¹
- Acute pancreatitis⁷
- Sedation-related complications^{8,10}
- Dental trauma¹⁰
- To decrease GI peristalsis, the anti-cholinergic agent hyoscine-N-butyl bromide (HBB) is used in gastrointestinal (GI) endoscopy. Side effects of HBB may include sleepiness, vision changes, dry mouth, rapid heart rate, triggering of glaucoma, and severe allergies.
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Fast and accurate visualization of inflammation, growths, ulcers, bleeding, and other abnormalities of the upper gastrointestinal (GI) tract.⁵
- Alternative EGD technique, such as nasal EGD, has been considered to reduce patients' discomfort and anxiety and avoid sedation-related adverse effects relative to peroral EGD.¹²
- Early detection, diagnosis, and surveillance of upper gastrointestinal malignancies.¹³
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Evidence

Sengupta et al. (2024) documented the recommendations of a panel of experts from the American College of Gastroenterology and the Society of Abdominal Radiology, comparing the advantages and limitations of endoscopic versus radiologic diagnostic examinations in patients with gastrointestinal bleeding. The authors noted that unless contraindicated, the evaluation of non-variceal upper gastrointestinal bleeding begins with EGD, with the ideal timing for the procedure being within 24 hours of presentation due to the increased risk of mortality when performed greater than 24-36 hours.³⁷

The European Society of Gastrointestinal Endoscopy (ESGE) published a technical review of endoscopic ultrasound in 2022. The authors discussed several scenarios wherein endoscopic ultrasound is the optimal diagnostic or therapeutic modality, such as the drainage of fluid collections, biopsy of suspicious lesions, and surveillance and staging of neoplasms.³⁸

A 2022 American Society of Gastrointestinal Endoscopy (ASGE) standards of practice review of adverse events associated with EGD found this procedure to be well-tolerated and safe, with more than 7 million esophagogastroduodenoscopies taking place each year in the United States. The overall incidence of the most insidious complications, including perforation, cardiopulmonary sequelae, and bleeding, remains extraordinarily low. Rates of perforation, for example, have been estimated at 1 in 25,000. Bleeding requiring emergency department care or inpatient stay for resolution has been evaluated at 80 in 100,000 patients within 30 days of the EGD.⁵

The American College of Gastroenterologists (ACG) and the American Gastroenterological Association (AGA) have published several recent guidelines pertaining to the use of EGD in high-volume clinical scenarios, such as peptic disease, Barrett's esophagus, and celiac disease. This robust guidance has been utilized where appropriate to synthesize this policy.^{1,6,24,26}

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Policy Revision History/Information

Original Date: February 6, 2025		
Review History		
Version 2	03/13/2025	Added previously missing CMS guidance (NCD 100.2, LCD L34434). Modified criteria so as not to be perceived as more stringent than CMS (i.e., loosed surveillance timeframe of non-dysplastic Barrett's to 1-3 years, utilized CMS language around peptic ulcer disease, simplified, added CMS indication for need for tissue/fluid sampling, simplified definition of "recent bleeding", utilized CMS indications for therapeutic EGD use, serial follow-up, and esophageal ultrasound). Rewrote medical evidence section for relevance. Added references
Version 2.1	10/07/2025	Updated CMS link and reference for L34434, A57063, A57414, and A56389- no content change Re-formatted document to current template version