



Surgery for Obstructive Sleep Apnea (OSA) in Adults Clinical Coverage Criteria

Overview

Obstructive sleep apnea refers to a medical condition in which the airflow rate during sleep is significantly reduced at varying percentages for more than 10 seconds. Hypopnea refers to when there is at least a 50% reduction for more than 10 seconds. Apnea refers to when there is 100% reduction in airflow for more than 10 seconds.

The reduction in airflow is measured by a polysomnography test which is an overnight laboratory sleep study consisting of the following tests EEG, EOG, EMG, oral and nasal thermistors to monitor airflow, pulse oximetry to monitor arterial oxygen saturation (SaO), and V1 telemetry to monitor cardiac activity.

Policy

This Policy applies to the following Fallon Health products:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for surgical treatment of obstructive sleep apnea (OSA). Medicare does not have an NCD for hypoglossal nerve stimulation for the treatment of OSA. National Government Services, Inc. does not have an LCD or LCA for the surgical treatment of OSA. National Government Services, Inc. has an LCD for Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387) and an LCA: Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (A57092) (MCD search 02/09/2022).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by

Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Fallon Health requires prior authorization for surgery for obstructive sleep apnea (OSA) in adults. Procedures include Uvulopalatopharyngoplasty (UPPP) and maxillomandibular advancement surgery (MMA). UPPP is considered a less invasive procedure, Fallon Health Medical Directors will review each request to see if the specific procedure is appropriate given the member’s condition. These requests must be supported by the treating provider(s) medical records.

All of the following criteria must be met:

1. Documentation of Moderate/Severe apnea by means of a polysomnography test conducted at an affiliated sleep disorders laboratory within the previous 12 months. (Documentation of Mild apnea may also meet eligibility criteria if the average O2 saturation is below 85%.)
2. Must be within 20% above their ideal body weight, defined as the number of pounds on the upper limit of the range of weights sorted by sex and height, EXCEPT for morbidly obese patients, defined as having a Body Mass Index of >40.
3. Trial and failure conservative therapy with a Continuous Positive Air Pressure (CPAP) device.

The Plan allows our affiliated sleep disorder laboratories to use the Apnea Index, Respiratory Disturbance Index, or Apnea Hypopnea Index with slight variations in rating definitions. The formulas for diagnosing the severity of sleep apnea are as follows:

Respiratory Disturbance Index (RDI) and Apnea Hypopnea Index (AHI) refer to the same formula:

$$RDI/AHI = \frac{\text{total number of apneas + hypopneas, including subtle hypopneas}}{\text{total number of sleep hours}}$$

Apnea Index (AI) is calculated using the following formula:

$$AI = \frac{\text{total number of apneas}}{\text{total number of sleep hours}}$$

| Level | Apnea Index (AI) “ of Episodes per Hour | | Respiratory Disturbance Index (RDI) or Apnea Hypopnea Index (AHI) |
|----------|--|----|---|
| Mild | 6-15 episodes/hour with average O2 saturation above 85% | or | > 5 < 15 |
| Moderate | 15-30 episodes/hour with average O2 saturation 80-85% | or | >15<30 |
| Severe | More than 30 episodes/hour with average O2 saturation below 80%. (However patients with an average O2 saturation below 85% and at least 6 episodes/hour of apnea may also meet the criteria for severe sleep apnea.) | or | >30 |

Exceptions to the above criteria include patients with a diagnosis of Mild OSA and one of the following:

1. Life threatening cardiac conditions independent of severity of apnea, OR
2. Who are intolerant or incapable of using a CPAP or BiPAP device with documentation of failed trials, or in severe cases of abnormal upper airway anatomical obstructions that preclude the use of a CPAP or BiPAP device.

Hypoglossal Nerve Stimulation

Fallon Health requires prior authorization for hypoglossal nerve stimulation including insertion/implantation, replacement or revision and removal of hypoglossal nerve neurostimulator and or related components.

Fallon Health Clinical Coverage Criteria

Hypoglossal nerve stimulation is an alternative for those who have failed or cannot tolerate standard treatments for (OSA) such as CPAP, oral appliances, or other surgeries. The system consists of 3 different components implanted with a neurostimulator placed on the hypoglossal nerve to control stimulation to moderate the patient's breathing cycle. The patient can control this system via a remote before and after sleeping. All of the following criteria must be met in order for approval:

1. The member must be 22 years or older; AND
2. Documentation of CPAP trial and failure; AND
3. Body Mass index (BMI) of less than 32 kg/m²; AND
4. Documentation of (PSG) testing; AND
5. AHI ≥ 15 with less than 25% central apneas.

Any other uses of hypoglossal nerve stimulation will be considered experimental and investigational.

Medicare members: Fallon Health follows coverage criteria in National Government Services, Inc. Local Coverage Determination (LCD) for Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387) and LCA: Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (A57092) for Medicare members, including members enrolled in Medicare Advantage, NaviCare and PACE plans.

LCD Link: [Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea \(L38387\)](#)

LCA Link: [Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea \(A57092\)](#)

Hypoglossal nerve stimulation using an FDA-approved hypoglossal nerve stimulator (e.g., Inspire® Upper Airway Stimulation, Inspire Medical Systems, Inc.) is considered medically reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea when all of the following criteria are met:

1. Beneficiary is 22 years of age or older; and
2. Body mass index (BMI) is less than 35 kg/m² ; and
3. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; and
4. Beneficiary has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and
5. AHI is 15 to 65 events per hour; and
6. Beneficiary has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert; and
7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; and

8. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

Hypoglossal nerve stimulation is considered not reasonable and necessary and therefore will be denied for the following:

1. Use for all other indications.
2. Non-FDA-approved hypoglossal nerve neurostimulation.
3. Presence of any of the following:
 - Beneficiaries with central and mixed apneas that make up more than one-quarter of the total AHI.
 - Beneficiaries with an implantable device could experience unintended interaction with the HGNS implant system. Limitations are:
 - BMI equal to or greater than 35
 - Neuromuscular disease affecting the respiratory system
 - Hypoglossal-nerve palsy
 - Severe restrictive or obstructive pulmonary disease
 - Moderate-to-severe pulmonary arterial hypertension
 - Severe valvular heart disease
 - New York Heart Association class III or IV heart failure
 - Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months)
 - Persistent uncontrolled hypertension despite medication use
 - An 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 HNS and report problems to the attending provider
 - Coexisting non-respiratory sleep disorders that would confound functional sleep assessment
 - Beneficiaries who are, or who plan to become pregnant.
 - Beneficiaries who require magnetic resonance imaging (MRI) with model 3024.
 - Beneficiaries, who require magnetic resonance imaging (MRI) with model 3028, can undergo MRI on the head and extremities if certain conditions and precautions are met. Please refer to the Manufacturer Guidelines for this model and future models for information.
 - Beneficiaries who are unable or do not have the necessary assistance to operate the sleep remote.
 - Beneficiaries with any condition or procedure that has comprised neurological control of the upper airway.
4. Drug Induced Sleep Endoscopy (DISE):
 - Due to documented inconsistency in determining if complete concentric collapse (CCC) is present, the inserting provider shall be certified by the FDA approved manufacturer's second opinion service of validation via video clip submissions of at least 80% agreement in at least 15 consecutive studies.
 - Inserting providers shall have documentation to submit to this contractor if necessary.
5. Shared Decision Making (SDM):
 - SDM, by definition, is any documented conversation between an attending provider and the patient, and not between multiple providers. Providers shall provide these documents if requested by the Plan.

Provider Qualifications - Hypoglossal nerve stimulation for the treatment of OSA must be ordered and furnished by qualified personnel.

- Insertion of an FDA-approved hypoglossal nerve stimulation device addressed in this LCD must be performed by a qualified physician (MD or DO) who is a board certified or a board eligible otolaryngologist having completed the appropriate AMA or AOA certified residency and/or fellowship program and maintains ongoing certification in otolaryngology. In addition, prior to implanting the system, surgeons will need to receive classroom instruction by an FDA

approved device manufacturer or equivalent on device implant techniques as well as cadaver training. Documentation must be provided to support completion of training to an exemplary level by the manufacturer.

- Sleep physicians and sleep technicians shall receive classroom instruction from a similar facility on how to titrate the device including hands on operation of the programmer. Doctors must maintain, for the Plan to review, documentation of such training completion to a satisfactory level of completion as established by the device manufacturer or appropriate board approval of competency. Evaluation, referral and post implant evaluation of the hypoglossal nerve stimulator, but not including expected post-op care by the inserting physician, should be performed by board eligible or certified sleep physician with qualifications as outlined in Article A53019, Polysomnography and Sleep Studies – Medical Policy Article. Sleep Technicians shall meet the same qualifications as outlined in the Article A53019, Polysomnography and Sleep Studies – Medical Policy Article, in addition. Likewise, sleep studies shall be performed in an accredited sleep facility as stated in Article A53019.

For coverage of oral devices please refer to Fallon Health’s policy Oral Appliances Obstructive Sleep Apnea.

Exclusions

- Services for patients that do not meet the medical criteria defined above
- Laser Assisted Uvulopalatoplasty (HCPCS S2080) is considered Experimental/Investigational
- Topographic EEG mapping
- Radiofrequency-mediated tongue tissue reduction

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

| Code | Description |
|-------|--|
| 21193 | Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft |
| 21194 | Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft) |
| 21195 | Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation |
| 21196 | Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation |
| 21198 | Osteotomy, mandible, segmental; |
| 21199 | Osteotomy, mandible, segmental; with genioglossus advancement |
| 21206 | Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard) |
| 21685 | Hyoid myotomy and suspension |
| 41599 | Unlisted procedure, tongue, floor of mouth |
| 42145 | Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty) |
| 42299 | Unlisted procedure, palate, uvula |
| D7941 | Osteotomy - mandibular rami. (See also codes 21193, 21195, 21196) |
| D7943 | Osteotomy - mandibular rami with bone graft; includes obtaining the graft. (See also code 21194) |
| D7945 | Osteotomy - body of mandible (See also codes 21193, 21194, 21195, 21196) |

Hypoglossal Nerve Stimulation

Claims for hypoglossal nerve stimulation must include primary diagnosis code G47.33 (Obstructive sleep apnea) and a secondary diagnosis code indicating the Body Mass Index (BMI) (i.e., Z68.1-Z68.34).

Effective for dates of service on or after January 1, 2022, CPT codes 64568 and 0466T have been replaced with CPT code 64582, and CPT codes 0467T and 0468T have been replaced with CPT codes 64583 and 64584, respectively.

For dates of service on or after 01/01/2022, the following CPT codes should be used to report insertion, replacement and removal of hypoglossal nerve neurostimulator:

- CPT code 64582 should be reported for insertion/implantation of hypoglossal nerve neurostimulator electrode, generator and breathing sensor electrode.
- CPT code 64583 should be used to report revision or replacement of hypoglossal nerve neurostimulator electrode and breathing sensor electrode with connection to existing generator

Use modifier 52 for revision or replacement of either the hypoglossal nerve stimulator electrode array or distal respiratory sensor.

- CPT code 64854 should be used to report removal of hypoglossal nerve neurostimulator electrode and generator and breathing sensor electrode

Use modifier 52 for removal of one or two components of the hypoglossal nerve stimulator electrode array, pulse generator, or distal respiratory sensor.

| Code | Description |
|-------|---|
| 64582 | Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array |
| 64583 | Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator |
| 64584 | Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array |

For dates of service prior to 01/01/2022:

Implantation of a hypoglossal nerve stimulator for treatment of OSA is billed with:

- CPT code 64568 - Incision for implantation of cranial nerve (e.g. vagus nerve) neurostimulator electrode array and pulse generator
- CPT code +0466T - Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (list separately in addition to code for primary procedure)

Revision or replacement of a hypoglossal nerve stimulator for treatment of OSA is reported with:

- CPT code 0467T - Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator

Removal of a hypoglossal nerve stimulator for treatment of OSA is reported with:

- CPT code 0468T - Removal of chest wall respiratory sensor electrode or electrode array

Coding Information

- CPT code 64568 is for both the neurostimulator and its corresponding electrode array.

- CPT codes 0466T, 0467T, and 0468T are codes for the insertion, revision or replacement, and removal respectively.

| Code | Description |
|-------|--|
| 64568 | Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator |
| 0466T | Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (list separately in addition to code for primary procedure) |
| 0467T | Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator |
| 0468T | Removal of chest wall respiratory sensor electrode or electrode array |

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Policy history

Origination date: 12/1995
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Technology Assessment Committee: 08/28/2013, 09/24/2014 (updated template, coding, specified MMA procedure, and references) 09/23/2015 (updated references), 09/15/2016 (updated references), 09/27/2017 (updated references), 08/22/2018 (updated references), 09/10/2019 (updated references), 10/23/2019 (added criteria for Hypoglossal Nerve Stimulation)

02/09/2022 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section; updated coding for hypoglossal nerve stimulation).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.