Hypoglossal Nerve Stimulation (Inspire® Upper Airway Stimulation) Clinical Coverage Criteria

Overview

Sleep-Disordered Breathing, often referred to as obstructive sleep apnea (OSA), is characterized by frequent episodes of apnea or hypopnea during sleep. Multiple detrimental physiologic changes may result from these apneic and hypopneic episodes. Non-surgical and surgical approaches to obstructive apnea and hypopnea have been developed.

Hypoglossal nerve stimulation is an alternative for those who have failed or cannot tolerate standard treatments for OSA such as CPAP. 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.

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

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.

Medicare Advantage
Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for surgery for hypoglossal nerve stimulation. Medicare does not have an NCD for hypoglossal nerve stimulation. National Government Services, Inc., the Part A and B Medicare Administrative Contractor with jurisdiction in the Plan's service area has an LCD for Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387) (Medicare Coverage Database search 07/22/2024).

Coverage criteria for surgery for hypoglossal nerve stimulation are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.

Link: **LCD Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387)**

MassHealth ACO
Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for hypoglossal nerve stimulation (MassHealth website search 07/22/2024), therefore, the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
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 Clinical Coverage Criteria apply to MassHealth ACO members, NaviCare members who do not meet coverage criteria in LCD Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387) and Community Care members.

Fallon Health considers hypoglossal nerve stimulation using the Inspire® Upper Airway Stimulation System (Inspire Medical Systems, Inc.) medically necessary for members who meet all of the following criteria :

1. Age 22 years or older with a diagnosis of moderate-to-severe OSA; AND
2. Documentation of PAP failure, or the member cannot tolerate PAP therapy; AND
3. Body Mass index (BMI) is ≤40 kg/m2; AND
4. A polysomnography (PSG) is performed within 24 months of first consultation for Inspire; AND
5. Apnea hypopnea index (AHI) is ≥ 15 and ≤ 100 with predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI).
6. Absence of complete concentric collapse at the soft palate level.

PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as:

(1) Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or
(2) Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).

Additionally, hypoglossal nerve stimulation may be covered for use in members between the ages of 18 and 21 with moderate to severe OSA (AHI ≥15 and ≤100), and members ages 13 to 18 with Down syndrome and AHI > 10 and < 50 who:

- Do not have complete concentric collapse at the soft palate level, and
- Are contraindicated for, or not effectively treated by, adenotonsillectomy, and
- Have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance, and
- Have followed standard of care in considering all other alternative/adjunct therapies.

Exclusions

- Hypoglossal nerve stimulation is considered experimental/investigational and not medically necessary when any of the following conditions are present:
  - Central + mixed apneas > 25% of the total apnea–hypopnea index (AHI)
  - Any anatomical finding that would compromise the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate
  - Any condition or procedure that has compromised neurological control of the upper airway
  - Patients who are unable or do not have the necessary assistance to operate the sleep remote
  - Patients who are pregnant or plan to become pregnant. UAS therapy has not been evaluated for safety or efficacy during pregnancy.
  - Patients with an implantable device that may be susceptible to unintended interaction with the Inspire system. Consult the device manufacturer to assess the possibility of interaction.
  - Patients who require magnetic resonance imaging (MRI) other than what is specified in the MR Conditional labeling

Summary of Evidence

The diagnosis of obstructive sleep apnea (OSA) involves measuring breathing during sleep, based upon polysomnogram (PSG). Due to the high prevalence of OSA, there is significant cost associated with evaluating all patients suspected of having OSA with PSG (currently considered the gold standard diagnostic test). Further, there also may be limited access to in-laboratory testing in some areas. Home sleep apnea testing (HSAT), which has limitations, is an alternative method to diagnose OSA in adults, and may be less costly and more efficient in some populations. Measurement error is inevitable in HSAT, compared against PSG, as standard sleep staging channels are not typically monitored in HSAT (e.g., EEG, EOG and EMG monitoring are not typically performed), which results in use of the recording time rather than sleep time to define the denominator of the respiratory event index (REI; the term used to represent the frequency of apneas and hypopneas derived from HSAT) (Kapur et al., 2017).

The third edition of the International Classification of Sleep Disorders (ICSD-3) defines OSA as a PSG-determined obstructive respiratory disturbance index (RDI) ≥ 5 events per hour associated with the typical symptoms of OSA (e.g., unrefreshing sleep, daytime sleepiness, fatigue or insomnia, awakening with a gasping or choking sensation, loud snoring, or witnessed apneas), or an obstructive RDI ≥ 15 events per hour (even in the absence of symptoms). In addition to apneas and hypopneas that are included in the AHI, the RDI includes respiratory effort-related arousals (RERAs) (AASM, 2014).

The scoring of respiratory events is defined in The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications, Version 2.3 (AASM Scoring Manual). However, it should be noted that there is variability in the definition of a hypopnea event. The AASM Scoring Manual recommended definition requires that changes in flow be associated with a 3% oxygen desaturation or a cortical arousal but allows an alternative definition that requires association with a 4% oxygen desaturation without consideration of cortical arousals. Depending on which definition is used, the AHI may be considerably different in a given individual. The discrepancy between these and other hypopnea definitions used in research

studies introduces complexity in the evaluation of evidence regarding the diagnosis of OSA (AASM, 2016).

AHI is the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure (PAP) device and can only be measured in a type 1 (facility-based polysomnogram) or type II home-based sleep study. RDI is the episodes of apnea and hypopnea per hour of recording without the use of PAP and is reported in type III or IV home sleep study (Kapur et al., 2017).

American Academy of Sleep Medicine

The American Academy of Sleep Medicine (AASM, 2021) published practice guidelines on the referral of adults with OSA for surgical consultation (Kent et al., 2021). These guidelines replaced the 2010 Parameters for the Surgical Modifications of the Upper Airway for Obstructive Sleep Apnea in Adults (Aurora et al., 2010). The AASM commissioned a task force of experts in sleep medicine, otolaryngology, and bariatric surgery to develop recommendations and assign strengths based on a systematic review of the literature and an assessment of the evidence using the GRADE process. The task force evaluated the relevant literature and the quality of evidence, the balance of benefits and harms, patient values and preferences, and resource use considerations that support the recommendations. The AASM Board of Directors approved the final recommendations. Each recommendations statement is assigned a strength ("Strong" or "Conditional"). A Strong recommendation is one that clinicians should follow under most circumstances. A Conditional recommendation is one that requires that the clinician use clinical knowledge and experience and strongly consider the patient's values and preferences to determine the best course of action.

The treatment of adults with OSA should be based on a diagnosis of OSA established using objective testing performed in conjunction with a comprehensive sleep evaluation. The AASM guidelines note that positive airway pressure (PAP) is the most efficacious treatment for OSA, but effectiveness can be compromised when patients are unable to adhere to therapy or obtain adequate benefit, which is when surgical management may be indicated. It is expected that surgery proceed only once the surgeon and patient have mutually agreed upon an acceptable risk profile. Inherent to this evaluation is the understanding that some referred patients will not be appropriate for surgical interventions and are expected to be counseled as such by surgical colleagues.

The AASM strongly recommends that clinicians discuss referral to a sleep surgeon with adults with OSA and body mass index (BMI) < 40 kg/m^2 who are intolerant or unaccepting of PAP. The strong recommendation to discuss surgical referral with patients with a BMI < 40 kg/m^2 is not a recommendation against (and does not preclude) discussion of surgical referral with patients with a BMI ≥ 40 kg/m^2 if the health care provider deems it an appropriate management discussion point.

For patients within the BMI range of 35–40 kg/m^2 who are intolerant or unaccepting of PAP, the AASM strongly recommends discussion regarding a referral to both sleep and bariatric surgeons to discuss management options. Other organizations, such as the National Heart, Lung, and Blood Institute, recommend consideration of bariatric surgery for individuals suffering from obesity (class II/III, BMI ≥ 35 kg/m2) and OSA, regardless of PAP adherence status.

The AASM guideline recommendations are based on a systematic review and meta-analysis of 274 studies of surgical interventions, including procedures such as uvulopalatopharyngoplasty (UPPP), modified UPPP, maxillomandibular advancement (MMA), tongue base suspension, and hypoglossal nerve stimulation. The systematic review deemed most included data of low quality, consisting of mostly observational data (Kent et al., 2021a).

A total of 4 RCTs and 239 observational studies investigated the use of surgery as rescue therapy for participants who were intolerant or unaccepting of PAP to improve 1 or more of the following outcomes: excessive sleepiness, quality of life (QOL), sleep quality, snoring, blood pressure (BP), perioperative death, permanent dysphagia, apnea-hypopnea index (AHI), respiratory disturbance index (RDI),lowest oxygen saturation (LSAT), and oxygen desaturation

index (ODI). Participants included in the studies had a BMI <40 kg/m^2. Participants in the RCTs had moderate to severe OSA and received UPPP with or without tonsillectomy. Participants in the control group originally received no treatment but were eventually treated with the same procedure(s). Participants in the observational studies represented a broad population of adults undergoing a wide variety of surgical interventions for OSA including palatal modification, tongue base resection, multilevel pharyngeal airway surgery, nasal surgery, maxillomandibular advancement, and hypoglossal nerve stimulation. The Task Force determined that the overall quality of evidence for the use of surgical treatments in patients who are intolerant or unaccepting of PAP was low based on the critical outcomes and downgrading of the evidence due to risk of bias associated with observational studies and imprecision within the RCTs.

Based on their combined clinical experience and the substantial effects of surgery on objective and subjective measures of disease, the Task Force judged that the potential benefits of a discussion regarding referral to a sleep surgeon with patients intolerant or unaccepting of PAP therapy outweigh the potential harms of untreated OSA. The Task Force observed that the balance of risks vs benefits for upper airway surgery is variable and dependent upon an individual patient's OSA severity, symptoms, medical comorbidities, and selected surgical therapy but noted that a discussion of individualized risks and benefits is a standard component of the preoperative informed consent process.

American Academy of Otolaryngology-Head and Neck Surgery Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA)

The American Academy of Otolaryngology-Head and Neck Surgery considers upper airway stimulation (UAS) via the hypoglossal nerve for the treatment of adult obstructive sleep apnea syndrome to be a safe and effective second-line treatment of moderate to severe obstructive sleep apnea in patients who are intolerant or unable to achieve benefit with positive pressure therapy.

Analysis of Evidence (Rational for Determination)

The evidence suggests surgical treatments including hypoglossal nerve stimulation are associated with improvements in clinical outcomes for adults with obstructive sleep apnea (OSA) who have failed or cannot tolerate positive air pressure (PAP) therapy. Given the proven safety and efficacy of PAP therapy in patients with OSA, surgery is not a first line therapy.

Coding

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

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

References

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Policy history

Origination date:	09/01/2024
Review/Approval(s):	Technology Assessment Committee: 07/23/2024, 09/24/2024 (annual review, criteria for hypoglossal nerve stimulation previously included in Surgery for Obstructive Sleep Apnea) UM Committee: 10/15/2024 (annual review)

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.