Subject: Hypoglossal Nerve Stimulator

Medical Policy #: 46.0

Original Effective Date: 07-28-2021

Status: Reviewed

Last Annual Review Date: 08-21-2024

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans, or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

History/Background and/or General Information

Obstructive sleep apnea (OSA) is a disease characterized by recurrent episodes of upper airway obstruction during sleep. The disruption in airflow caused by OSA has been associated with multiple comorbidities, including hypertension, cardiovascular disease, cardiac arrhythmia, cerebrovascular disease, excessive daytime sleepiness, and mood disorders. Continuous positive airway pressure (CPAP) has long been the primary treatment modality of choice for OSA, showing improvements in many comorbidities. Unfortunately, despite attempts to improve compliance, many people are unable to tolerate treatment with CPAP. Because of the large percentage of patients not tolerating CPAP, alternative treatment strategies are necessary.

The hypoglossal nerve is the twelfth cranial nerve and innervates all the extrinsic and intrinsic muscles of the tongue, except for the palatoglossus which is innervated by the vagus nerve. It is a nerve with a solely motor function. The nerve arises from the hypoglossal nucleus in the brain stem as a number of small rootlets, passes through the hypoglossal canal and down through the neck, and eventually branches within the tongue and innervates the tongue. There are two hypoglossal nerves in the body: one on the left, and one on the right.

The concept of stimulating the tongue musculature to increase upper airway size and limit the pathophysiologic obstruction leading to OSA was introduced in the late 1980s. A variety of strategies were utilized, including transcutaneous stimulation with placement of electrodes in the submental region, sublingual mucosa, and soft palate. However, these studies were limited by their lack of selective stimulation of the primary protrusor of the tongue, the genioglossus muscle. In 2001, Schwartz et al performed a trial in which they selectively stimulated the branches of the hypoglossal nerve, innervating the genioglossus. They noted a significant improvement in the apnea-hypopnea index (AHI) and O2 desaturation nadir. This technology was subsequently refined, and in 2014 the Stimulation Therapy for Apnea Reduction (STAR) trial was published as the initial clinical trial using upper airway stimulation (UAS) as an alternative therapy to CPAP for treatment of OSA.

The only Food and Drug Administration (FDA) - approved hypoglossal nerve stimulation (HGNS) system has three implantable components: a stimulation lead that delivers mild stimulation to maintain multilevel airway patency during sleep, a breathing sensor lead that senses breathing patterns, and a generator that monitors breathing patterns. The two external components are a patient sleep remote that provides a noninvasive means for a patient to activate the generator and a physician programmer that allows the physician to noninvasively interrogate and configure the generator settings. The system battery life for the implantable components is 7 to 10 years.

A surgeon implants the system containing a neurostimulator subcutaneously in the patient's chest, with one lead attached to the patient's hypoglossal nerve (cranial nerve XII) at the base of the tongue and one lead implanted in the patient's chest. The lead in the chest consists of a pressure sensor that detects breathing. Information about respiration rate is relayed to the device, which stimulates the hypoglossal nerve in the tongue. When stimulated, the tongue moves forward, opening the airway. The patient can operate the device by remote control, which the patient activates before going to sleep. The device turns on after 20 minutes to minimize disrupting the patient's sleep onset; the device must be manually turned off via remote when the patient wakes.

Coverage Determination

Prior Authorization is required.

Members are allowed one in-laboratory sleep study with titration post Hypoglossal Nerve Implantation. Additional requests for in-lab sleep study with titration will require MDR review for medical necessity.

For Medicare, Medicaid and Commercial.

A. Covered indications for adults:

FDA-approved **(e.g., Inspire)** hypoglossal nerve neurostimulation is considered medically reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea in adults when **all** of the following criteria are met:

1. Age ≥18 years; **AND**
2. Body mass index (BMI) <40 kg/m^2; **AND**
3. Apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI), (15 ≤ AHI ≤ 100) with less than 25% central apneas; **AND**
4. Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night including documentation that the patient was intolerant of PAP), despite multiple models of facial masks and nasal pillows, and consultation with a sleep specialist; **AND**
5. Absence of the following:
    a. Complete concentric collapse at the soft palate level.
    b. Severe or restricted obstructive pulmonary disease.
    c. Neuromuscular disease affecting the respiratory tract.
    d. Severe valvular heart disease.
    e. Pregnancy or planned pregnancy.
    f. Any other anatomical findings that would compromise performance of the device (e.g., tonsil size 3 or 4 per tonsillar hypertrophy grading scale).

B. Covered indications for adolescents:

Hypoglossal nerve stimulation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** in adolescents or young adults with Down syndrome and obstructive sleep apnea (OSA) when **ALL** the following criteria are met:

1. Age 13 to 17 years; **AND**
2. Body mass index < 95th percentile for age; **AND**
3. AHI ≥10 and ≤50 with less than 25% central apneas and history of adenotonsillectomy; **AND**
4. Have either tracheotomy or ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device; **AND**
5. Non-concentric retropalatal obstruction on drug-induced sleep endoscopy.

Limitations

The following are considered not reasonable and necessary and therefore will be denied:

1. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for all other indications.
2. Non-FDA-approved hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for the treatment of adult obstructive sleep apnea due to insufficient evidence of being safe and effective.
3. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary when any of the following contraindications are present:
    - 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.
    - BMI equal to or greater than 40 for adults.
    - Neuromuscular disease.
    - 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 could interfere with the patient's ability to operate the HNS and report problems to the attending provider.
    - Coexisting nonrespiratory 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 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 more 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 compromised 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 this contractor.

Place of Service (POS)

Hypoglossal nerve stimulation for the treatment of OSA must be furnished in accordance with the accepted standards of medical practice in a setting appropriate to the patient's medical needs and condition.

Provider Qualifications

Hypoglossal nerve stimulation for the treatment of OSA must be ordered and furnished by qualified personnel. The hypoglossal nerve (HN) may be damaged during neck surgeries. A detailed understanding of the anatomy of the hypoglossal nerve in relation to various anatomical landmarks and surrounding structures is important to reduce procedural complications and the risk of nerve damage.

- Provider Specialties
  - Insertion of hypoglossal nerve stimulation 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 a residency and/or fellowship program and maintains ongoing certification in otolaryngology.
  - Insertion of an FDA-approved hypoglossal nerve stimulation device must be performed by a qualified physician who completed the appropriate AMA or AOA certified residency program 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 program. Doctors must maintain, for the contractor 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 LCD L35050, Outpatient Sleep Studies. In addition, Sleep Technicians shall meet the same qualifications as outlined in the LCD L35050, Outpatient Sleep Studies. Likewise, sleep studies shall be performed in an accredited sleep facility as stated in LCD L35050.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT code	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

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee (PHCQC): Clinton White MD
Medical Director: Jim Romero MD
Date Approved: 08/21/2024
Reviewed by Specialist:

- Fouad Reda, MD, Medical Director, Presbyterian Sleep Medicine – Kaseman, Date: January 25, 2024

References

1. Novitas, LCD Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38385), Effective date: 03/15/2020, [Cited 07/15/2024]
2. Novitas, LCA Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea LCA (A56938), Revision date: 01/01/2022, R4. [Cited 07/15/2024]
3. MCG A-0973, Hypoglossal Nerve Stimulation, Implantable, 28th Edition, Last Update: . [Cited 07/15/2024]
4. Hayes: Hypoglossal Nerve Stimulation For The Treatment Of Obstructive Sleep Apnea, Evidence Analysis Research Brief Aug 28, 2023. [Cited 07/15/2024]
5. Hayes: Hypoglossal Nerve Stimulation For The Treatment Of Obstructive Sleep Apnea, Health Technology Assessment, Oct 30, 2018 | Annual review Dec 27, 2022 [Cited 07/16/2024]
6. Hayes, Hypoglossal Nerve Stimulation (Inspire Upper Airway Stimulation; Inspire Medical Systems Inc.) For Treatment Of Obstructive Sleep Apnea, Health Technology Assessment, Nov 6, 2014 | Annual Review: Sep 28, 2015. {Cited 07/16/2024]
7. Wellmark Medical Policy 07.01.68. Implantable Hypoglossal Nerve Stimulation for the treatment of OSA. Effective date 5/2015, Last Review Date 8/2023. [07/15/2024]
8. Premera Blue Cross, Medical Policy 7.01.101, Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome. Effective date 9/1/2023. Last review 8/21/2023. 07/15/2024]
9. FDA approval indications for Inspire Upper Airway Stimulation P130008/S090. [07/15/2024]
10. Shalini Paruthi, MD. Management of obstructive sleep apnea in children. UTD 7/18/2023. [07/15/2024]
11. American Academy of Sleep Medicine. International Classification of Sleep Disorders, third ed, text revision, American Academy of Sleep Medicine, 2023. [07/15/2024]

Publication History

07-28-21	New Policy. Reviewed by Technology Assessment Committee (TAC) on April 06, 2021 who agreed to creating a medical policy for Commercial, Medicaid and Medicare. Reviewed by PHP Medical Policy Committee on 06/09/2021.The medical policy to follow LCD L38385 for all Product lines. Currently Inspire is approved by FDA. Due to high cost CPT codes: 64568, 0466T, 0467T and 0468T will require PA for all LOB.
07-27-22	Annual review. Reviewed by PHP Medical Policy Committee on 06/22/2022. Continue to follow LCD (L38385) for all LOB. Codes were updated in LCA (A56938), as follow. The CPT code 64568 has been removed from the article and replaced with CPT code 64582. Add these new codes 64582, 64583, 64584 to policy which will also be added to require PA. Codes deleted on Jan 01, 2022 per AMA: 0466T, 0467T, 0468T which will be removed from policy and PA grid. LCA removed code 64568 which will be removed from policy but will continue to require PA. Configuration: OPPS has status indicator as -N- for C1767, C1778, C1787 - Paid under OPPS; payment is packaged into payment for other services. Therefore, there is no separate APC payment.
07-26-23	Annual review. Reviewed by PHP Medical Policy Committee on 05/03/2023. Continue to follow LCD (L38385) for all LOB. Codes 64582, 64583, and 64584 will continue to require PA. **Updated on 10/20/2023**: Reviewed by PHP Medical Policy Committee on 10/18/2023. Removed to follow LCD L38385 for ALOB. Wrote homegrown criteria which is less restrictive than the LCD for adults; and developed criteria for adolescents with Down Syndrome and Obstructive Sleep Apnea (OSA) for ALOB: For adults: Change age from 22 to ≥ 18 years. BMI changed from 35 to ≤40 kg/m2; AHI change from 15 to 65 events per hour/(15 ≤ AHI ≤ 100; combined #4 and #5 to #3 "Apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI), (15 ≤ AHI ≤ 100) with less than 25% central apneas";" additional language added to #6 to include "…documentation that the patient was intolerant of PAP for a minimum of 12 weeks, despite multiple models of facial masks and nasal pillows, and consultation with a sleep specialist"; added more to absence of conditions, such as severe or restricted obstructive pulmonary disease; neuromuscular disease affecting the respiratory tract; severe valvular heart disease; pregnancy or planned pregnancy; and any other anatomical findings that would compromise performance of the device (e.g., tonsil size 3 or 4 per tonsillar hypertrophy grading scale). Continue PA requirement for ALOB. For children: added criteria for adolescents age (13 to 17) that is specific to Downs syndrome and OSA with BMI ≤ 95th percentile for age; and AHI ≥10 and ≤50 with less than 25% central apneas and history of adenotonsillectomy; and have either tracheotomy or ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device; and Non-concentric retropalatal obstruction on drug-induced sleep endoscopy. Removed the ICD-10 table, since we are not following CMS. **Updated on 01/04/2024:** Correction made to the Limitation section regarding BMI which was erroneously left as "equal to or greater than 35" when it should be "≥40" for adults and the removal of "12 weeks" under section A(4). **Updated on 01/26/2024:** Fouad Reda, MD reviewed policy. **Updated on 02/14/2024**: Added clarifying language that one sleep study after Hypoglossal Nerve Implantation is allowed and after that will need MDR review for medical necessity.
08-21-24	Annual review. Reviewed by PHP Medical Policy Committee on 07/24/2024. Correction to homegrown criteria for adult and peds for Commercial, Medicaid and Medicare. Correction for adult BMI, was changed from less than or equal ≤40 to less than <40. For peds, BMI changed from less than or equal to ≤95 percentile to less than <95 percentile. Continue to require PA for 64582, 64583, 64584 for ALOB for both adults and peds to protect patient safety so to generate better health outcomes.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.