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Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea Policy Indication/Usage:

The only Food and Drug Administration (FDA)-approved hypoglossal nerve stimulation (HGNS) system consists of 3 implanted components: a small implanted pulse generator (IPG), a respiratory sensing lead, and a stimulating lead surgically placed on the hypoglossal nerve. The IPG is subcutaneously implanted beneath the clavicle in the upper chest and delivers HGNS via the stimulating lead. The sensing lead is placed in the intercostal space and contains a piezoelectric differential pressure sensor for detecting respiratory signals. The IPG synchronizes stimulation of the hypoglossal nerve with the patient's breathing cycle using input from the sensing lead. The device may be activated 4 to 6 weeks after surgical implantation and the stimulation is titrated to yield ideal outcomes coupled with minimal side effects for each patient. The patient uses a remote control to turn the device on before going to sleep and turn it off upon awakening.

Medical Indications for Authorization Commercial Members

SummaCare considers an FDA-approved hypoglossal nerve neurostimulation system medically necessary for the treatment of moderate to severe obstructive sleep apnea when ***ALL*** of the following criteria are met:

- Member is 18 years of age or older
- Body mass index (BMI) is less than 35 kg/m2
- A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant
- Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI)
- Apnea hypopnea index (AHI)) of 15 to 65 events per hour
- Member has a minimum of one month of CPAP monitoring 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);
- absence of a complete concentric collapse at the soft palate level on drug induced sleep endoscopy
- no anatomical finding that would compromise the performance of upper airway stimulation

CPT code 64582 insertion of hypoglossal nerve neurostimulator electrode, generator and breathing sensor electrode

CPT code 64583 revision or replacement of hypoglossal nerve neurostimulator electrode and breathing sensor electrode with connection to existing generator

CPT code 64854 removal of hypoglossal nerve neurostimulator electrode and generator and breathing sensor electrode

Medicare Members

CMS

CGS LCD ID L38307 Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea Coverage Guidance Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

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 passes up again over the tongue muscles it supplies into 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.

Covered Indications

FDA-approved hypoglossal nerve neurostimulation is considered medically reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea when **all** of the following criteria are met:

- Beneficiary is 22 years of age or older; **and**
- Body mass index (BMI) is less than 35 kg/m^2; **and**
- A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; **and**
- Beneficiary has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **and**
- AHI is 15 to 65 events per hour; **and**
- 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**
- Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; **and**
- No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

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 35
    - 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 would 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.

Limitations

SummaCare considers hypoglossal nerve neurostimulation experimental and investigational for all other indications. SummaCare also considers non-FDA-approved hypoglossal nerve neurostimulation experimental and investigational for the treatment of adult obstructive sleep apnea

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

Cardiac Event Detection Monitoring CMS. https://www.cms.gov/medicare-coveragedatabase/view/lcd.aspx?lcdid=34953&ver=27&

Agency for Healthcare Research and Quality (AHRQ). Remote cardiac monitoring. Technology Assessment. Prepared for the AHRQ by the ECRI Evidence-based Practice Center (EPC). Contract No. 290-02-0019. Rockville, MD: AHRQ; December 12, 2007.

Baquero GA, Banchs JE, Ahmed S, et al. Surface 12 lead electrocardiogram recordings using smart phone technology. J Electrocardiol. 2015;48(1):1-7.

Barrett PM, Komatireddy R, Haaser S, et al. Comparison of 24-hour Holter monitoring with 14day novel adhesive patch electrocardiographic monitoring. Am J Med. 2014;127:95.e11-95.e17.

Brignole M, Moya A, de Lange FJ, Deharo JC, Elliott PM, Fanciulli A, et al. 2018 ESC Guidelines for the diagnosis and management of syncope. Eur Heart J. 2018 Jun 1;39(21):1883- 1948

Derkac WM, Finkelmeier JR, Horgan DJ, Hutchinson MD. Diagnostic yield of asymptomatic arrhythmias detected by mobile cardiac outpatient telemetry and autotrigger looping event cardiac monitors. J Cardiovasc Electrophysiol. 2017 Dec;28(12):1475-1478

Hayes, Inc. Evidence Analysis Research Brief. Patient Use of Mobile Medical Applications for Detection of Cardiac Arrhythmias. Hayes, Inc.; February 2020

Hayes, Inc. Evolving Evidence Review. Clinical utility of mobile medical applications for detection of cardiac arrhythmia episodes. Lansdale, PA: Hayes, Inc.; June 2021

Noubiap JJ, Agbaedeng TA, Kamtchum-Tatuene J, et al. Rhythm monitoring strategies for atrial fibrillation detection in patients with cryptogenic stroke: A systematic review and meta-analysis. Int J Cardiol Heart Vasc. 2021 Apr 16;34:100780.

Olson JA, Fouts AM, Padanilam BJ, Prystowsky EN. Utility of mobile cardiac outpatient telemetry for the diagnosis of palpitations, presyncope, syncope, and the assessment of therapy efficacy. J Cardiovasc Electrophysiol. 2007 May;18(5):473-7.

Rothman SA, Laughlin JC, Seltzer J, et al. The diagnosis of cardiac arrhythmias: A prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. J Cardiovasc Electrophysiol. 2007;18(3):241-247