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

Clinical Guidelines for Medical Necessity Review

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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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Other Notices:

Guideline Information:

Specialty Area: Otolaryngology
Guideline Name: Hypoglossal Nerve Stimulation (HGNS) Implantable Device

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Type: [**X**] Adult (18+ yo) | [**X**] 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)
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- Billing and Coding: Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea (A58075)
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- Billing and Coding: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (A57092)
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- 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/m^2; **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/m^2; **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]

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.[12]

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.[17]

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.[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 Airwar Stimulation device) and found consistent improvements in OSA outcomes across device types, all reporting stable patient outcome results 12 months after implantation.[18]

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Clinical Guideline Revision History/Information

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