Cohere Medical Policy - Hypoglossal Nerve Stimulation (HGNS) Implantable Devices

Clinical Guidelines for Medical Necessity Review

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Guideline Information:

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

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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Service: Hypoglossal Nerve Stimulation Implantable Devices

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).[1] 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.[2] 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 the condition is a contraindication for HGNS.[3] To be eligible for HGNS, patients must be diagnosed with moderate to severe OSA using the apnea-hypopnea index (AHI) standards, and unable to tolerate or adhere to CPAP therapy.[4]

An HGNS implantable device may migrate or become infected.[5] Other adverse outcomes associated with the implantation, while rare, include pneumothorax, pleural effusion, and the device lead drifting into the pleural space. Some patients may also experience discomfort from or intolerance to the HGNS stimulation.[6] Furthermore, 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.[7] Wollny et al (2024) conducted a systematic review of adverse events and complications that resulted from HGNS implantation. The authors concluded that the procedure has a positive patient safety profile while identifying a variety of adverse events and side effects, including tongue abrasion, post-operative pain, neuropraxia, and hematoma.[8] Increased healthcare costs and complications may result from the inappropriate use of emergency services and additional treatments.

Medical Necessity Criteria

Indications

- ➔ **A hypoglossal nerve stimulation (HGNS) implantable device** is considered appropriate if **ALL** of the following are **TRUE**[6,9-13]:
  - ◆ Clinically documented failure of, or intolerance to, continuous positive airway pressure (CPAP) therapy; **AND**
  - ◆ The absence of **ANY** of the following anatomical findings that may inhibit the upper airway stimulation[6]:
    - Complete concentric collapse at the soft palate level by a drug-induced sleep endoscopy (DISE)[9,10]; **OR**
    - Tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale[9]; **AND**
  - ◆ **ANY** of the following[11]:
    - The patient is 18 years of age or older and has **ALL** of the following:
      - Body mass index (BMI) less than 35 kg/m^2; **AND**
      - AHI shows 15 to 65 events per hour with less than 25% central and mixed apneas[12]; **OR**
    - The patient is 13-18 years of age with Down syndrome and has **ALL** of the following[13]:
      - BMI less than or equal to the 95th percentile for individual's age and gender; **AND**
      - A polysomnography (PSG) or home sleep apnea study demonstrating <25% central events.

Non-Indications

- ➔ **A hypoglossal nerve stimulation implantable device** is not considered appropriate if **ANY** of the following is **TRUE**[6,13]:
  - ◆ The patient has **ANY** of the following:
    - Anatomical findings that would compromise the performance of the device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale)[6,13]; **OR**
    - Body mass index (BMI) greater than 35 kg/m^2; **OR**
    - Complete concentric collapse at the soft palate level[9,10,14]; **OR**
    - Central apneas that make up more than 25% of total AHI[13,14]; **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[13]; **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.

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

Medical Evidence

Bellamkonda et al. (2021) conducted a Food and Drug Administration database analysis of adverse events in hypoglossal nerve stimulator implantation, identifying 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.[7]

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 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.[1]

A systematic review and meta-analysis conducted by Constantino et al. (2020) 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.[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.[16]

A cohort study of 85 patients receiving HGNS sought to determine and compare the improvements associated with HGNS to patient-rleated 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.[17]

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