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The Department of Vermont Health Access Clinical Criteria

Subject: Hypoglossal Nerve Stimulation (HGNS) for the Treatment of Obstructive Sleep Apnea
Last Review: February 22, 2024*
Past Revisions: N/A

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

Obstructive sleep apnea (OSA) occurs when there are recurrent episodes of partial (hypopnea) or complete (apnea) closure of the upper airway leading to interruption or cessation of breathing. Continuous positive airway pressure therapy (CPAP) is the most frequently utilized treatment. The two most common initial modes of PAP administration include auto-titrating PAP (APAP) and fixed-level CPAP. Other modes that are less commonly used include bilevel PAP (BiPAP) and rarely adaptive servo-ventilation (ASV). APAP is commonly utilized when home sleep testing is diagnostic.

Some patients are unable to tolerate these forms of positive airway pressure therapy. When clinically appropriate, hypoglossal nerve stimulation (HGNS) offers an alternative modality for the treatment of OSA for patients that meet criteria. HGNS treats OSA by stimulating the upper airway. Implementation of HGNS involves surgical implantation of a system containing a neurostimulator under the skin, 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.

Some studies have shown that individuals with complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure are not favorable candidates for HGNS.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertain to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules

7102.2 Prior Authorization Determination
4.101 Medical Necessity for Covered Services
4.104 Medicaid Non-Covered Services
4.106 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

Coverage Position

HGNS may be covered for members:

- When the device is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont's Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding HGNS and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

Coverage Criteria

The Department of Vermont Health Access (DVHA) aligns coverage criteria with the Centers for Medicare and Medicaid (CMS) Local Coverage Determination (LCD) L38528 guidelines as included below with the inclusion of the 2023 FDA expanded indications for FDA-approved HGNS devices. Therefore, HGNS is considered medically reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea when all of the following criteria are met:

Age 22 and older with moderate to severe obstructive sleep apnea, and

1. Body mass index (BMI) is less than or equal to 40 kg/m2; AND
2. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; AND
3. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); AND
4. AHI is 15 to 100 events per hour; AND
5. Member 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) despite consultation with a sleep expert and addressing issues of nonadherence such as poorly fitting mask, air leaks, inadequate therapy, often due to insufficient pressure or mode to meet the patient's need which may be due to weight gain, inadequate initial titration, new medications, or device malfunction; AND
6. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; AND

7. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).
8. Certain devices are FDA approved for individuals aged 18-21 who meet the above criteria and have moderate to severe OSA (AHI greater or equal to 15- less than or equal to 100)

Age 13-18

1. Individual has Down's Syndrome (DS); AND
2. AHI greater than 10 and less than 50 who:
    a. Do not have complete concentric collapse at the soft palate level
    b. Are contraindicated for or not effectively treated by adenotonsillectomy
    c. Have been confirmed to fail, or cannot tolerate PAP therapy despite attempts to improve compliance: AND
    d. Have been considered for all other alternative/additional treatments that are considered standard of care for this condition.

HGNS services for members under the age of 18 will require DVHA physician review.

Contraindications:

Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary when any of the following contraindications are present:

- Members with central and mixed apneas which make up more than one-quarter of the total AHI.
- Anatomical finding that would compromise the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate
- Members with an implantable device could experience unintended interaction with the HGNS implant system.
- BMI equal to or greater than 40
- Neuromuscular disease
- Hypoglossal-nerve palsy
- Rhabdomyolysis
- 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 HGNS and report problems to the attending provider.
- Coexisting non-respiratory sleep disorders that would confound functional sleep assessment
- Members who are, or who plan to become pregnant.

- Members who require Magnetic Resonance Imaging (MRI) with specific HGNS devices. Please refer to the manufacturer's guidelines for device/model specifics.
- Members who are unable or do not have the necessary assistance to operate the sleep remote.
- Members with any condition or procedure that has compromised neurological control of the upper airway

Provider Specialties

- Insertion of hypoglossal nerve stimulation must be performed by a qualified physician (MD or DO) who is a board-certified otolaryngologist having completed a residency and/or fellowship program and maintains ongoing certification in otolaryngology.
- Providers performing insertion of an FDA - approved HGNS device should receive instruction on implant technique from an FDA-approved device manufacturer or equivalent. Documentation from device implantation training may be requested for coverage of services.
- Additionally, sleep physicians and sleep technicians working with individuals on titration of devices should have training specific to the device for titration.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence-based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

A replacement or revision of an implantable hypoglossal nerve stimulation (generator, leads and/or battery) may be considered medically necessary for an individual who meets criteria and the existing device is no longer under warranty and cannot be repaired.

Type of service or procedure covered

FDA-approved hypoglossal nerve neurostimulation when the above criteria are met.

Type of service or procedure not covered (this list may not be all inclusive)

HGNS systems that are experimental, investigational, and non-FDA approved will not be covered.

Coding guidelines

The DVHA follows coding for hypoglossal nerve neurostimulation in line with CMS Local Coverage Article (LCA) A57092.

Please see the Medicaid Portal at http://vtmedicaid.com/#/feeSchedule for fee schedules, code coverage, and applicable requirements.

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