CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines: Hypoglossal Nerve Stimulation for CarePartners of Connecticut

Effective: March 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers blow.	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 857-304-6463

☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 857-304-6463

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

For the service of Treating Obstructive Sleep Apnea with a hypoglossal nerve stimulator, evidence is sufficient for coverage. The criteria used for hypoglossal nerve stimulator below is based upon the Stimulation Treatment for Apnea Reduction (STAR) study and current FDA guidance to provide additional guidance for Members with OSA.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan may cover hypoglossal nerve stimulation implantation procedures when documentation confirms **ALL** of the following criteria are met:

1. Member is 22 years of age and older; **and**
2. Member's Body Index (BMI) is less than or equal to 40 kg/m^2
3. Member has undergone a polysomnography (PSG) within 24 months of the first consultation for a HGNS implant
4. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total Apnea-Hypopnea Index (AHI)); **and**
5. AHI is between 15 to 100 events per hour; **and**
6. Member has demonstrated 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 with the Member's physician that the Member was intolerant to CPAP despite consultation with a sleep specialist; **and**
7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; **and**
8. No other anatomical findings that would comprise performance of device (e.g., tonsil size 3 or 4 per standardized hypertrophy scale).

Limitations

The Plan considers implantation of a hypoglossal nerve stimulator as investigational for the following conditions:

1. 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.
2. Members with central and mixed apneas that make up more than one-quarter of the total AHI.

3. Members with an implantable device could experience unintended interaction with the HGNS implant system.
4. BMI greater than 40
5. Neuromuscular disease
6. Hypoglossal-nerve palsy
7. Severe restrictive or obstructive pulmonary disease
8. Moderate-to-severe pulmonary arterial hypertension
9. Severe valvular heart disease
10. New York Heart Association class III or IV heart failure
11. Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months)
12. Persistent uncontrolled hypertension despite medication use
13. 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.
14. Coexisting non-respiratory sleep disorders that would confound functional sleep assessment
15. Members who are, or who plan to become pregnant.
16. Members who are unable or do not have the necessary assistance to operate the sleep remote.
17. Members with any condition or procedure that has compromised neurological control of the upper airway.

Codes

The following codes require prior authorization:

Table 1:

Code	Description
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
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

References:

1. https://www.fda.gov/medical-devices/recently-approved-devices/inspire-upper-airway-stimulation-p130008s090
2. U.S. Food and Drug Administration (FDA) Premarket Approval (PMA) for the Inspire II Upper Airway Stimulator. Supplemental order SO21
3. Hayes A TractManager Company. Hypoglossal Nerve Stimulation for the Treatment of Obstructive Nerve Stimulation. Health Technology Assessment. October 30, 2018. Annual Review December 27, 2022. Last accessed November 21, 2024
4. Woodson BT, Strohl KP, Soose RJ, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes. Otolaryngol Head Neck Surg. 2018 Jul; 159 (1):194-202.
5. Heiser C, Steffen A, Boon M, et al. Post-approval upper airway stimulation predictors of treatment effectiveness in the ADHERE registry. Eur Respir J 2019; 53: 1801405.
6. Withrow K, Evans S, et.al. Upper Airway Stimulation Response in Older Adults with Moderate to Severe Obstructive Sleep Apnea. Otolaryngol Head Neck Surg 2019; 1-6
7. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) for Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387). Last accessed on November 1, 2024 at cms.gov/medicare-coverage

Approval And Revision History

December 18, 2024: Reviewed by the Medical Policy Approval Committee (MPAC) as a new Medical Necessity Guideline – service moved from CMS LCD to internal criteria, effective March 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the

individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment, or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.