MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea OH MCD-MM-1253	12/01/2023
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea

B. Background

Obstructive Sleep Apnea (OSA) is a chronic disorder characterized by recurrent episodes of upper airway obstruction during sleep. The untreated disruption of airflow caused by OSA is associated with multiple comorbidities, such as nocturnal hypoxemia, cardiac arrhythmia, hypertension, an increased risk of cardiovascular disease, cessation of breathing, loud snoring, and daytime sleepiness. Continuous positive airway pressure (CPAP) therapy, which delivers oxygen in a continuous stream independent of whether the patient is inhaling or exhaling a breath, has been the mainstay therapy for treatment of OSA. However, despite its efficacy and manufacturers' redesigns to make the devices more comfortable, a large percentage of patients are unable to tolerate CPAP therapy, and adherence is low. As a result, 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 hypoglossal nerve stimulator (HNS) is an implanted medical device that works to reduce the occurrence of OSA by electrically stimulating the hypoglossal nerve to the tongue. 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 twenty (20) minutes to minimize disrupting the patient's sleep onset. The device must be manually turned off via remote when the patient wakes.

C. Definitions

- **Drug Induced Sleep Endoscopy (DISE)** - A diagnostic tool to assess the upper airway of snorers and obstructive sleep apnea patients in conditions that mimic natural sleep. 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 requested.

- **Hypoglossal Nerve** - The twelfth cranial nerve that stimulates all the extrinsic and intrinsic muscles of the tongue, except for the palatoglossus, which is stimulated by the vagus nerve.
- **Obstructive Sleep Apnea (OSA)** - A disease characterized by recurrent episodes of upper airway obstruction during sleep.

D. Policy

I. CareSource considers hypoglossal nerve stimulation for the treatment of moderate to severe OSA medically necessary when **ALL** of the following clinical criteria is met:

A. A pulmonary specialist, internal medicine provider or sleep medicine specialist verifies the member is eligible for treatment; and

B. If the member has a cardiac condition, this requires clearance from a cardiologist; and

C. The member is 18 years of age or older; and

D. Body mass index (BMI) is less than 35 kg/m2; and

E. An in-lab or home sleep study has been performed no more than 24 months before the first consultation of the HGNS implant, and there has not been a change of body weight by 10% or more from the time of that diagnostic sleep study; and

F. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total apnea-hypopnea index (AHI); and

G. AHI is 15 to 65 events per hour; and

H. Member has documentation that demonstrates BiPAP or CPAP failure:

1. Defined as AHI greater than 15 despite CPAP usage; or
2. CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned)
3. Shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert; and

I. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; and

J. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

II. CareSource considers the following not medically reasonable and necessary and will be denied:

A. Hypoglossal nerve neurostimulation is considered not medically reasonable and necessary for all other indications;

B. 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 safety and efficacy;

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

1. Members with central and mixed apneas that make up more than one-quarter of the total AHI;
2. Members with an implantable device could experience unintended interaction with the HGNS implant system;

3. BMI equal to or greater than 35;
4. Neuromuscular disease;
5. Hypoglossal-nerve palsy;
6. Severe restrictive or obstructive pulmonary disease;
7. Moderate-to-severe pulmonary arterial hypertension;
8. Severe valvular heart disease;
9. New York Heart Association Class III or IV heart failure;
10. Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months);
11. Persistent uncontrolled hypertension despite medication use;
12. An active, serious mental illness that reduces the ability to carry out Activities of Daily Living (ADLs) and would interfere with the member's ability to operate the HNS and report problems to the attending provider;
13. Coexisting non-respiratory sleep disorders that would confound functional sleep assessment;
14. Members who are, or who plan to become pregnant;
15. Members who require Magnetic Resonance Imaging (MRI) with Inspire model 3024;
16. Members who require MRI with Inspire 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);
17. Members who are unable or do not have the necessary assistance to operate the sleep remote;
18. Members with any condition or procedure that has compromised neurological control of the upper airway.

E. Conditions of Coverage

NA

F. Related Policies/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	02/16/2022	New Policy
Date Revised	02/15/2023	Lowered age to 18 to make less restrictive. Added BiPAP.
Date Effective	12/01/2023	
Date Archived		

H. References

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2. Baptista, Peter M et al. Hypoglossal Nerve Stimulation in the Treatment of Obstructive Sleep Apnea: Patient Selection and New Perspectives. Nature and Science of Sleep vol. 12 151-159. Retrieved January 6, 2023 from www.ncbi.nlm.nih.gov.
3. Centers for Medicare and Medicaid Services. LCD - Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38307) (04/01/2020). Retrieved January 6, 2023 from www.cms.gov.
4. Eisenberg D, Shikora SA, Aarts E, et al. 2022 American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): Indications for Metabolic and Bariatric Surgery. Surg Obes Relat Dis. 2022;18(12):1345-1356. Retrieved February 15, 2023 from www. pubmed.ncbi.nlm.nih.gov.
5. Tietjens JR, Claman D, Kezirian EJ, et al. Obstructive Sleep Apnea in Cardiovascular Disease: A Review of the Literature and Proposed Multidisciplinary Clinical Management Strategy. J Am Heart Assoc. 2019;8(1):e010440. Retrieved January 6, 2023 from www.ncbi.nlm.nih.gov.

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Approved by ODM 09/07/2023