KAISER PERMANENTE® Mid-Atlantic States	**Hypoglossal Nerve Stimulator for Obstructive Sleep Apnea** **Medical Coverage Policy**

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please consult the Medicare Coverage Database.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. **Procedure: Hypoglossal Nerve Stimulator (HNS) for Treatment of Obstructive Sleep Apnea**

II. **Specialties:** Sleep Study Medicine, Otolaryngology, DME

III. **Clinical Guidelines**

A. Clinical Indications for Referral

Hypoglossal Nerve Stimulator (HNS) is considered medically necessary for the treatment of Obstructive Sleep Apnea (OSA) when **ALL** of the following criteria are met:

1. Patient is 18 years of age or older; **and**
2. Body Mass Index (BMI) is less than 35 kg/m2; **and**
3. A sleep study evaluation is performed with polysomnography (PSG) or a home sleep study in the last 24 months. The sleep study result should demonstrate moderate to severe obstructive sleep apnea with apnea-hypopnea index (AHI) of 15-65 events per hour within 24 months of initial consultation for HNS implant; **and**
4. Has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **and**
5. Shared Decision-Making (SDM) between the patient, sleep physician, and qualified otolaryngologist (if they are not the same) who determines that the patient demonstrates failure or intolerance to Positive Airway Pressure (PAP) treatments such as continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BiPAP) with the following requirements:
   - **a.** PAP failure is defined as inability to eliminate OSA with AHI greater than 15 despite PAP usage; or
   - **b.** PAP intolerance is defined as:
     - **i.** PAP machine-derived compliance reporting with usage of:
       1) less than 4 hours a night; or
       2) less than 5 nights per week of usage; or
     - **ii.** Unwillingness to use PAP (such as returning the PAP system after attempting to use it) despite CPAP interface and/or setting optimizations; **and**
6. Confirmed absence of complete concentric collapse at the soft palate level by a drug-induced

sleep endoscopy (DISE) procedure; **and**

7. Absence of anatomical findings that would compromise performance of device (such as tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale); **and**
8. Not considered a candidate for surgical removal of adenoids and tonsils (adenotonsillectomy); **and**
9. Absence of any HNS contraindicated condition such as severe obstructive or restrictive lung disease and significant cardiovascular disease including CHF (Congestive Heart Failure), pulmonary hypertension or valvular heart disease. Please refer to section IV-B for the list of HNS contraindications; **and**
10. The HNS device to be used for treatment of OSA has Food and Drug Administration (FDA) approval; **and**
11. HNS must be furnished in accordance with the accepted standards and medical practice in a setting (either inpatient or outpatient setting) appropriate to the patient's medical needs and condition; **and**
12. Patients under age 18 will be considered on a case-by-case basis e.g., Down's syndrome

B. Documentation

The following documentation are required for patient evaluation and medical appropriateness determination for HNS:

1. Medical history and physical examination notes;
2. Conservative treatment of OSA has failed;
3. CPAP trial result;
4. Sleep Study result in the last 12 months including apnea-hypopnea index (AHI) score; and
5. Drug-induced sleep endoscopy (DISE) result

IV. Limitation and Contraindication

A. Limitations

Hypoglossal Nerve Stimulator is **not** considered medically necessary for any of the following:

1. Other indications other than those cited in section III A; and
2. If the patient does not meet all the criteria cited in section III; and
3. Mild Obstructive Sleep Apnea (OSA); and
4. The Drug-Induced Sleep Endoscopy (DISE) screening reveal a complete concentric collapse at the retropalatal airway; or
5. Patients who are looking for an alternative approach despite successfully using CPAP or other alternative/additional treatments considered as standard of care for OSA; or
6. Non-FDA-approved HNS device for treatment of OSA.

B. Contraindications

Hypoglossal Nerve Stimulator is contraindicated in the presence of **any** of the following:

1. BMI 40 kg/m2 or greater; or
2. Patient who is or who plans to become pregnant; or
3. Any anatomical finding that would compromise or prevent the performance of upper airway stimulation such as the presence of complete concentric collapse of the soft palate; or
4. Hypoglossal-nerve palsy; or
5. Rhabdomyolysis; or
6. Presence of neuromuscular or neurologic disease such as muscular dystrophy, Parkinson's or dementia that compromise the neurological control of the upper airway; or
7. Presence of a condition as a result from a procedure or previous treatment that compromise the neurological control of the upper airway such as previous surgery or radiation to larynx, throat, or tongue; or
8. Central and mixed apneas that make up more than 25% of the total apnea-hypopnea index (AHI); or
9. Coexisting non-respiratory sleep disorders that would confound functional sleep assessment;
10. Severe insomnia; or
11. Complete blockage of the upper airway; or
12. Severe restrictive or obstructive pulmonary disease; or
13. Hypoventilation from any cause; or
14. Prolonged hypoxia; or
15. Moderate-to-severe pulmonary arterial hypertension; or
16. Severe valvular heart disease; or
17. New York Heart Association class III or IV heart failure; or
18. Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months); or
19. Persistent uncontrolled hypertension despite medication use; or
20. Severe co-morbid condition; or
21. Those who require magnetic resonance imaging (MRI) other than what is specified in the MR conditional labeling for Inspire UAS system; or
22. Have another implantable device that may be susceptible to unintended interaction with Inspire UAS (the manufacturer of the device must be consulted to assess the possibility of interaction); or
23. Patient who is unable to operate the remote for HNS or does not have the necessary assistance to operate the HNS device's external programmer; or
24. Acute psychiatric disorder or unstable psychological status

V. Replacement of HNS device

Replacement of HNS is medically necessary when there is documentation that the stimulator and/or generator is malfunctioning, cannot be repaired, or no longer under warranty.

VI. Description

Hypoglossal Nerve Stimulation (HNS) is a sleep apnea treatment that involves surgical implantation of a medical device for treatment of moderate to severe obstructive sleep apnea (OSA). It consists of implanted system components including implantable pulse generator (IPG), stimulation lead and sensing lead, and external components such as the physician programmer and the patient remote. The IPG detects the patient's respiratory effort during inspiration and helps maintain airway patency during sleep by mildly stimulating the hypoglossal nerve, activating the genioglossus muscle in a rhythm synchronized with the patient's breathing.

Inspire Upper Airway Stimulation (UAS) is currently the only FDA-approved implantable HND device. It is manufactured by Inspire Medical Systems Inc. which received FDA approval in 2014. **On June 8, 2023, FDA approved the device with expanded indication to include an updated upper limit baseline for apnea-hypopnea index (AHI) of 100 (increase from <65 to <100) and an upper limit threshold for recommended body mass index (BMI) of 40 (increase from ≤32 to ≤40).**

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
09/27/2023	09/27/2023
09/26/2024	09/26/2024

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.