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Hypoglossal Nerve Stimulator for Obstructive Sleep Apnea

Audience
Medical Management

Purpose
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Definition
<p>Obstructive sleep apnea (OSA) is a disorder characterized by obstructive apneas, hypopneas, and/or respiratory effort-related arousals caused by repetitive collapse of the upper airway during sleep. The estimated prevalence in North America is approximately 15 to 30 percent in males and 10 to 15 percent in females when OSA is defined broadly as an apnea-hypopnea index (AHI) greater than five events per hour of sleep. When more stringent definitions are used (e.g., AHI \geq5 events per hour plus symptoms or AHI \geq15 events per hour), the estimated prevalence is approximately 15 percent in males and 5 percent in females.</p>

Patients who meet the criteria for a diagnosis of OSA are traditionally classified as having mild, moderate, or severe disease based on their AHI and symptoms. Multiple treatment options exist. Mild disease is defined as having an AHI of 5-14. Moderate disease has an AHI of 15-30, and severe disease has an AHI >30. Mild disease is most often treated with positive pressure therapy or oral appliances.

Several therapeutic options are available for treating moderate-to-severe OSA, including continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BiPAP, upper airway surgery, oral appliances, and upper airway stimulation. The most proven and effective treatment for OSA is continuous positive airway pressure CPAP or BiPAP. However, some patients fail or are intolerant of CPAP or BiPAP therapy. Many other invasive and noninvasive therapy choices are considered depending on the patient's characteristics.

Hypoglossal nerve stimulation is one surgical option for the treatment of moderate-to-severe OSA in adult patients. This therapy includes an implantable device with three components: a small implanted pulse generator, a respiratory-sensing lead, and a stimulating lead surgically placed on the hypoglossal nerve.

It activates the tongue's protrusion muscles via the hypoglossal nerve to open the lower pharyngeal airway. It also improves the upper pharyngeal airway by physiological and anatomical coupling of the tongue to the palate, as long as the upper pharynx does not have a concentric collapse pattern. Thus, stimulation has a combined upper and lower pharyngeal airway effect in appropriately selected patients. The device is activated remotely each night during sleep and deactivated in the morning.

Patients younger than age 22 are not eligible for this therapy, nor is anyone with a body mass index >32, enlarged tonsils, or documentation of concentric airway collapse with sleep.

Policy/Procedure

- 1.** Mountain Health Co-Op Health Plans considers Food and Drug Administration (FDA)-approved hypoglossal nerve stimulators medically necessary in adults with moderate-to-severe OSA when ALL the following criteria are met:
 - 1.1** Age \geq 22 years
 - 1.2** AHI \geq 15 with less than 25% central apneas
 - 1.3** A minimum of 3-month trial of CPAP with documentation demonstrating CPAP failure (residual AHI \geq 20 or inability to tolerate CPAP \geq 4 hours per night for \geq 5 nights per week) or inability to tolerate CPAP;
 - 1.4** Body mass index (BMI) \leq 32 kg/m²
 - 1.5** Absence of complete concentric collapse* at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure
 - 1.6** No anatomical finding would compromise the performance of upper airway stimulation (e.g., tonsil size 3 or 4 per tonsillar hypertrophy grading scale).

**Concentric collapse decreases the success of hypoglossal nerve stimulation and is an exclusion criterion from the Food and Drug Administration.*

- 2. Mountain Health Co-Op Health Plans considers Food and Drug Administration (FDA)-approved hypoglossal nerve stimulators on young adults or adolescents diagnosed with moderate to severe OSA and Down syndrome medically necessary if ALL the following criteria are met (2.1-2.5).**
- 2.1** Age 10 to 21 years
 - 2.2** AHI >10 and <50 with less than 25% central apneas after prior adenotonsillectomy; AND
 - 2.3** Have either tracheotomy or noted to be ineffectively treated with CPAP due to ONE of the following:
 - a)** Noncompliance,
 - b)** Discomfort,
 - c)** Un-desirable side-effects,
 - d)** Persistent symptoms despite compliance use, or
 - e)** Refusal to use the device
 - 2.4** Body mass index less than or equal to the 95th percentile for age
 - 2.5** Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (DISE).

Mountain Health Co-Op Health Plans considers hypoglossal nerve stimulation experimental/ investigational for all other indications not listed above.

3. Clinical Rationale

- 3.1** In 2019 (latest review December 2022), Hayes, Inc. reviewed the evidence for using hypoglossal nerve stimulation therapy to treat moderate-to-severe OSA. The review suggests that the treatment is relatively safe and may reduce the severity of OSA and improve patient-reported outcome measures (i.e., excessive daytime sleepiness, function, quality of life) for patients with OSA who have failed or are intolerant to CPAP therapy. HGNS may provide a treatment option for patients with moderate-to-severe OSA for whom continuous positive airway pressure cannot provide relief. Still, the procedure may carry risks for complications and post-implantation surgical procedures.
- 3.2** Therefore, uncertainty remains due to the low quality of the evidence and the challenges in performing high-quality comparative studies in patients who are refractory to the standard of care for OSA (CPAP). More robust, higher-quality research is necessary to establish this therapy's efficacy firmly and identify the patients most likely to benefit from the intervention. Nonetheless, it is unlikely that higher-quality evidence will become available unless hypoglossal nerve stimulation becomes indicated for patients with less severe OSA.
- 3.3** Supporting the Hayes findings, studies by Strollo et al. (2015), Soose et al. (2016), and Gillespie et al. (2017), respectively, report findings of the STAR trial at 18 months, 24 months, and 48 months. These studies assessed AHI and ODI as primary endpoints and identified statistically significant improvement compared to no therapy but lack comparison to oral appliances or other methods to treat OSA. The serial studies suggest some level of effectiveness and safety of hypoglossal nerve stimulation related to AHI, ODI, and sleep quality measures, with some level of durability in these effects. However, these studies also suggest residual clinical disease, which may reduce the clinical impact of this therapy.

- 3.4** In addition, a 2015 systematic review and meta-analysis (Certal et al.) assessed the evidence regarding the efficacy and safety of hypoglossal nerve stimulation as an alternative therapy in the treatment of OSA. Poor adherence to continuous positive airway pressure treatment in obstructive sleep apnea (OSA) adversely affects the effectiveness of this therapy. Six prospective studies with 200 patients were included in this review. At 12 months, the pooled fixed effects analysis demonstrated statistically significant reductions in AHI, ODI, and ESS mean difference of -17.51 (95% CI: -20.69 to -14.34); -13.73 (95% CI: -16.87 to -10.58), and -4.42 (95% CI: -5.39 to -3.44), respectively. Similar significant reductions were observed at 3 and 6 months. Overall, the AHI was reduced between 50% and 57%, and the ODI was decreased between 48% and 52%. Despite using different hypoglossal nerve stimulators in each subgroup analysis, no significant heterogeneity was found in any comparisons, suggesting equivalent efficacy regardless of the system. In conclusion, the authors found that hypoglossal nerve stimulation therapy may be considered in selected patients with OSA who fail medical treatment. Although the authors noted that further studies comparing hypoglossal nerve stimulation with conventional therapies are needed to evaluate outcomes definitively,
- 3.5** A recent study has emerged on the efficacy and safety of hypoglossal nerve simulator therapy in children with Down Syndrome (DS) who have persistent severe OSA following an adenotonsillectomy (Diercks et al., 2018). Participants were six children and adolescents (12-18 years) with DS and severe OSA (apnea-hypopnea index [AHI] > 10 events/h) despite prior adenotonsillectomy and were often unable to tolerate CPAP. The authors concluded that hypoglossal nerve stimulation was tolerated and effective in this study population. This represents a potential therapeutic option for patients with DS and refractory OSA after adenotonsillectomy, as they frequently cannot tolerate CPAP devices.
- 3.6** According to Costantino et al., as of 2019, no RCTs were available that compared hypoglossal nerve stimulation (HGNS) to CPAP or other surgical therapies. Most available HGNS studies are prospective, retrospective, or case series. The authors concluded that the limited available evidence shows that HGNS has obtained a high surgical success rate with a reasonable long-term complication rate related to the device implanted. Furthermore, the procedure represents an effective and safe surgical treatment for moderate-severe OSA in selected adult patients > 22 years of age who had difficulty accepting or adhering to CPAP.
- 3.7** A safety study of Hypoglossal nerve stimulation (HNS) detailed 20 children with Down Syndrome and severe OSA (AHI of 10 or greater) who were treated at three tertiary care centers (Caloway et al., 2020). Included were non-obese (BMI < 95%) children and adolescents aged 10-21 years who were refractory to tonsillectomy and either unable to tolerate CPAP or dependent on a tracheostomy. For patients whose AHI was between 10 and 50 on baseline PSG, the median baseline AHI was 24.15 (interquartile range [IQR] of 19.88 to 35.10). All of the patients tolerated the stimulation, and two months after implantation, the median AHI was 3.56 (IQR 2.61 to 4.40). Success, defined as an AHI of 5 or less (mild) with HNS, was achieved in 14 of 20 patients (70%). The median percent reduction in AHI was 85%, with a median usage of 9.21 h (IQR: 8.29 to 9.50) per night. The OSA-18 score improved by 1.15

(IQR: 0.02 to 1.97), indicating a moderate but clinically significant change. Two adverse events were related to the extrusion or connectivity of the stimulation or sensation leads, which were corrected with wound exploration surgery. The authors concluded that overall, these data suggest that pediatric HGN stimulation appears to be a safe and effective therapy for children with DS and refractory severe OSA. However, a study in a larger population of children with Down Syndrome is ongoing.

3.8 In 2020, a multicenter prospective observational study (Thaler et al.) detailed the outcomes of the ADHERE Registry. This international study followed outcomes of upper airway stimulation (UAS) therapy in patients who have failed continuous positive airway pressure therapy for OSA. The registry enrolled adult participants who met the approved indications of UAS, including AHI, between 15 to 65 events per hour, intolerant to CPAP, and free of complete concentric collapse during sedated endoscopy. The average age was 60 years, with a BMI of 29.3 kg/m², and 74% male. A total of 97% of participants reported a history of positive airway pressure use for the treatment of OSA: 20% with oral appliances, 22% with nasal procedures, 29% with palatal procedures, and 5% with tongue-base procedures. Demographic and sleep study data collection occurred at baseline, implantation visit, post-titration (6 months), and final visit (12 months). Patient and physician-reported outcomes were collected. Predictors of therapy response were defined as $\geq 50\%$ decrease in AHI and AHI ≤ 20 at the 12-month visit. The registry has enrolled 1,017 patients from October 2016 through February 2019. Currently, 640 patients have completed their six-month follow-up, and 382 have completed the 12-month follow-up. After 12 months, the median AHI was reduced from 32.8 to 9.5. Epworth Sleepiness Scale was similarly improved from 11.0 to 7.0. Therapy usage was 5.6 ± 2.1 hours per night after 12 months. Only the female sex and lower baseline body mass index remained significant predictors of therapy response. Stimulation-related discomfort was reported by 12% of participants at six months and 8% of participants at 12 months post-implantation. Surgical intervention was required for device revision in three cases: one participant due to stimulation electrode dislodgement within six months and another two individuals with stimulation electrode repositioning within 12 months. A reported limitation of this study is that both home and in-laboratory studies were used in the analysis, with an attendant lack of uniformity of AHI recording. Home sleep studies may underestimate AHI. In conclusion, the authors found that UAS therapy significantly improves subjective and objective OSA outcomes. Also, this multi- international study shows that the therapy effect is durable and adherence is high.

3.9 As of 2017, the National Institute for Health and Care Excellence (NICE) noted hypoglossal nerve stimulation as a treatment for moderate to severe OSA. However, they state that it should only be used with special arrangements for clinical governance, consent, audit, or research, as evidence of its efficacy and safety is limited in quantity and quality.

3.10 The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Foundation issued a position statement in 2019 stating that it considers upper airway stimulation via the hypoglossal nerve to be an effective second-line treatment of moderate-to-severe OSA in adult patients who are intolerant of or unable to achieve benefit with positive airway pressure. However, not all

adult patients are candidates for this therapy; appropriate polysomnographic, age, body mass index, and objective upper airway evaluation measures are required for proper patient selection. The AAO-HNS Foundation does note that its position statements are based on an informal process of expert or committee consensus that draws upon the best available evidence but is not a formal technology assessment.

3.11 On April 14, 2020, the FDA PMA supplemental document for Inspire UAS (P130008 S039) had an approval order statement for the Inspire Upper Airway Stimulation. The device treats a subset of patients with moderate to severe OSA (AHI of greater than or equal to 15 and less than or equal to 65). Inspire UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level. PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

- a) Inability to use PAP (greater than five nights per week of usage; usage defined as greater than 4 hours of use per night) or
- b) Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it). Inspire UAS is also indicated for use in patients between the ages of 18 and 21 with moderate to severe OSA ($15 \leq \text{AHI} \leq 65$) who:
 - i. Do not have complete concentric collapse at the soft palate level;
 - ii. Are contraindicated for or not effectively treated by adenotonsillectomy;
 - iii. Have been confirmed to fail or cannot tolerate PAP therapy despite attempts to improve compliance; and
 - iv. Have followed the standard of care in considering all other alternative/adjunct therapies.

3.12 The FDA warnings and precautions section of the labeling documents from 2014 states that a BMI greater than 32 was not studied as part of the pivotal trial. Therefore, it may be associated with a decreased likelihood of response to treatment. The use of Inspire UAS in higher BMI patients is not recommended due to unknown effectiveness and safety.

Applicable Coding

CPT Codes

Covered if coverage criteria met

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 the existing pulse generator
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

HCPCS Codes

No applicable codes

Vendors

- HPS
- Personify

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Review/Revision/Approval History

Date	Description
06/01/2024	New Policy
03/09/2026	Reviewed by Mountain Health CO-OPs Policy Committee

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