Hypoglossal Nerve Stimulator for Obstructive Sleep Apnea

Policy MP-004

Origination Date: 04/22/2020
Reviewed/Revised Date: 05/01/2020
Next Review Date: 05/01/2021
Current Effective Date: 070/1/2020

Disclaimer:
1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, and Healthy U (Medicaid) plans. Refer to the “Policy” section for more information.

Description:
Obstructive sleep apnea (OSA) is a disorder that is 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 ≥5 events per hour plus symptoms or AHI ≥15 events per hour), the estimated prevalence is approximately 15 percent in males and 5 percent in females.

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

Several therapeutic options are available for the treatment of 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. In those instances, many other invasive and noninvasive therapy choices are considered depending on the patient’s characteristics.

Hypoglossal nerve stimulation is one surgical option that may be used for the treatment of moderate-to-severe OSA in adult patients. This therapy includes an implantable device with 3 components: a small implanted pulse generator, a respiratory-sensing lead, and a stimulating lead that are surgically placed on the hypoglossal nerve.
It activates the protrusion muscles of the tongue 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 properly selected patients. The device is activated remotely each night at the time of 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 with documentation of concentric airway collapse with sleep.

Policy Statement and Criteria

1. Commercial Plans

**U of U Health Plans does NOT cover hypoglossal nerve stimulation for obstructive sleep apnea (OSA) or any other indication, as it is considered investigational and/or not medically necessary.**

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at [http://health.utah.gov/medicaid/manuals/directory.php](http://health.utah.gov/medicaid/manuals/directory.php) or the [Utah Medicaid code Look-Up tool](http://health.utah.gov/medicaid/manuals/directory.php)

3. Medicare Plans

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicare policies and coverage, please visit their search website at: [http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&) or the [manual website](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&)

Clinical Rationale

In 2019, Hayes, Inc. reviewed the body of evidence for use of hypoglossal nerve stimulation therapy as a treatment of moderate-to-severe OSA. The review suggests that the therapy 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 that have failed or are intolerant to CPAP therapy. However, 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 firmly establish the efficacy of this therapy and to identify the patients that are 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.
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 again 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 as it relates to AHI, ODI and sleep quality measures with some level of durability to these effects. However, these studies also suggest residual clinical disease which may reduce clinical impact of this therapy.

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 reduced between 48% and 52%. Despite using different hypoglossal nerve stimulators in each subgroup analysis, no significant heterogeneity was found in any of the comparisons, suggesting equivalent efficacy regardless of the system in use. 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 went on to note further studies comparing hypoglossal nerve stimulation with conventional therapies are needed to definitively evaluate outcomes.

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

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.

**Applicable Coding**

**CPT Codes**

*Not covered*

**0466T** Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)

**0467T** Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator

**0468T** Removal of chest wall respiratory sensor electrode or electrode array
Not covered when specified as an implantation of a hypoglossal nerve stimulator

64568 Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator (Not covered when specified as an implantation of a hypoglossal nerve stimulator)

64569 Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator (Not covered when specified as an implantation of a hypoglossal nerve stimulator)

64570 Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator (Not covered when specified as an implantation of a hypoglossal nerve stimulator)

64999 Unlisted procedure, nervous system (Not covered when specified as an implantation of a hypoglossal nerve stimulator)

HCPCS Codes
No applicable codes

References:
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