Medical Policy Reference Manual
Medical Policy

7.01.130 Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea

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Description

Obstructive sleep apnea (OSA) syndrome is a serious and potentially life-threatening condition that is characterized by repetitive episodes of upper airway obstruction that occur during sleep, usually associated with a reduction in blood oxygen saturation. The Apnea/Hypopnea Index (AHI) is a scale that is used to determine whether sleep apnea is present and the severity. AHI is the total number of events (apnea or hypopnea) per hour of recording time during a sleep study. An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow compared with baseline, and with at least a 4% oxygen desaturation. Untreated OSA can result in poor quality of sleep and can be characterized by a variety of clinical presentations which correlate with the severity of hypoxemia during sleep. Symptoms can include excessive sleepiness (somnolence), disordered sleep, loud snoring, observed episodes of halted breathing during sleep, abrupt awakenings accompanied by gasping or choking. Difficulty concentrating during the day is also associated with OSA which can result in decreased motor and perceptual skills, school failure, metabolic dysfunction, increased risk of cardiovascular disease, depression, and mortality. The syndrome is most common in middle-aged, obese, people but can occur at any age including children.

Continuous positive airway pressure (CPAP) is currently the standard of care for moderate to severe OSA (Hayes, 2021). CPAP machines assist patients to breathe more easily during sleep by delivering continuous pressurized air that prevents the airway from collapsing during rest.

Hypoglossal nerve stimulation systems may be considered for patients who have tracheostomies or have been ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device.

Hypoglossal nerve stimulation systems consist of three components which are surgically implanted under general anesthesia. An implantable pulse generator (IPG) is placed subcutaneously below the clavicle and connects to the stimulation lead and the sensing lead. An implantable neurostimulator lead that delivers an electrical current to the hypoglossal nerve (cranial nerve XII) is positioned in a cuff around the hypoglossal nerve and connects to the IPG. A respiratory sensing lead is placed between the external and internal intercostal muscle (4th or 5th intercostal space). When therapy is on, the sensing lead detects the patient's respiratory effort and maintains airway patency with mild stimulation of the hypoglossal nerve leading to the contraction of the genioglossus muscle, the major muscle responsible for tongue protrusion. This electrical charge moves the tongue forward, dilates the pharyngeal region, improving the diameter of the upper airway, reducing collapsibility at both the level of soft palate and base of the tongue thereby relieving airway obstruction during sleep. Therapy settings are stored and configured by the physician using an external programmer.

Drug induced endoscopy (DISE) is used as a diagnostic and evaluation tool to determine the treatment plan for OSA and whether a patient is a suitable candidate for Hypoglossal Nerve Stimulation Device (Inspire®). DISE is a procedure that simulates natural sleep via unconscious sedation by infusing sedative agents like propofol and introducing a flexible endoscope into the upper airway to observe for obstruction. DISE can detect which specific structures play a leading role in airway obstruction and whether the blockage in breathing is occurring in the palate and/or tongue region(s). The results will suggest either a flat, anterior-posterior collapse or complete concentric collapse at the soft palate. Concentric collapse decreases the success of hypoglossal nerve stimulation and is an exclusion criterion by the Food and Drug Administration for the use of the Inspire® Upper Airway Stimulation, a hypoglossal nerve stimulation (HGNS) device.

Policy

Food and Drug Administration (FDA) approved hypoglossal nerve stimulation (e.g., Inspire® Upper Airway Stimulation (UAS) system) may be **medically necessary** as outlined in the Policy Guidelines.

Hypoglossal nerve stimulation that does not meet the below criteria is considered **not medically necessary** for the treatment of OSA.

Policy Guidelines

Hypoglossal nerve stimulation (e.g., Inspire® Upper Airway Stimulation (UAS) system) may be **medically necessary** in adults with obstructive sleep apnea syndrome (OSA) when the member meets the following criteria:

- Age 22 years and older; AND
- Apnea/Hypopnea Index (AHI) greater than or equal to 15 with less than 25% central sleep apneas; AND
- CPAP failure (residual AHI greater than or equal to 15 or failure to use CPAP greater than or equal to 4 hours per night for greater than or equal to 5 nights per week) or inability to tolerate CPAP; AND
- Body Mass Index less than or equal to 32 kg/m^2; AND
- Nonconcentric retropalatal obstruction on drug-induced sleep endoscopy

Hypoglossal nerve stimulation (e.g., Inspire® Upper Airway Stimulation (UAS) system) may be **medically necessary** in adolescents or young adults with Down syndrome and OSA when the member meets the following criteria:

- Age 10 to 21 years; AND
- Apnea/Hypopnea Index (AHI) greater than 10 and less than 50 with less than 25% central apneas after prior adenotonsillectomy; AND
- Have either tracheostomy or be ineffectively treated with CPAP due to non-compliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device; AND
- Body Mass Index less than or equal to 95th percentile for age; AND
- Nonconcentric retropalatal obstruction on drug-induced sleep endoscopy

Rationale:

2022 Update: A review of the peer-reviewed literature was performed for the period of August 2019 through October 2022. Current findings in the literature reveals use of HGNS for treatment of moderate-to-severe OSA suggests that the intervention is safe and may decrease the severity of OSA and improve patient-reported outcome measures (excessive daytime sleepiness, function, quality of life) for patients with OSA that have failed or are intolerant to CPAP therapy (Hayes, 2021). Per medical director decision the policy statement was revised. “Non-FDA approved hypoglossal nerve stimulation devices are considered experimental / investigational as it does not meet TEC criteria # 1-5” was removed. The medically necessary policy statement remains unchanged.

2019 Update: A review of the peer-reviewed literature was performed for the period of January 2017 through August 2019. Current findings in the literature, although lacking in quality (e.g., trial design, comparative effectiveness), suggests that hypoglossal nerve stimulation for the treatment obstructive sleep apnea (OSA) leads to improvements in OSA severity (e.g., Apnea/Hypopnea Index (AHI) and Oxygen Desaturation Index). The 2016 positioning statement from the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) endorsed the use of hypoglossal nerve stimulation (upper airway stimulation) as an effective second-line treatment for adults with moderate to severe obstructive sleep apnea who are unable to tolerate or achieve benefit with positive pressure therapy (PAP). The AAO-HNS also recommends careful selection of patients using polysomnographic, age, BMI, and objective upper airway evaluation measures to guide proper selection. Taking into consideration the variability in treatment outcomes/results and the morbidity associated with OSA patients who undergo traditional surgeries due to failed PAP therapy, the literature findings to-date, and recommendations from the AAO-HNS/clinical input, the policy statement was revised to now include medically necessary indications for hypoglossal nerve stimulation for the treatment of OSA.

2017 Update: There is limited evidence to support the efficacy, safety, and long-term outcomes of HGNS for the treatment of OSA. The optimal patient selection criteria for this device have not been defined. Randomized controlled trials and/or comparative effectiveness trials with long-term follow-up, comparing HGNS to establish procedures are necessary to evaluate the effectiveness of this technology.

Benefit Applications

The purpose of this Medical Policy Reference Manual is to provide clinical criteria and/or local, state, or federal coverage requirements for applicable services, devices, and drugs. Specific contract provisions, restrictions, and exclusions will

take precedence over the clinical criteria, as the member contract supersedes clinical criteria adopted by CareFirst. Always check the member's contract for benefits.

Provider Guidelines

There are no Provider Guidelines for this Medical Policy.

Cross References to Related Policies and Procedures

2.01.018	Sleep Disorders, Policy
7.01.025	Spinal Cord and Deep Brian Stimulation, Policy
7.01.031	Archived Sacral Nerve Stimulation for Treatment of Urinary Continence Disorders, Policy
7.01.041	Treatments for Urinary Incontinence, Policy
7.01.075	Vagus Nerve Stimulation, Policy
7.01.134	Phrenic Nerve Stimulation for the Treatment of Central Sleep Apnea, Policy

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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