

Subject: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea		Original Effective Date: 6/17/2020
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DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina clinical policy document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL^{2 30}

Obstructive Sleep Apnea (OSA) is a chronic disorder characterized by repetitive collapse of the oropharyngeal airway during sleep, with resultant nocturnal hypoxemia, recurrent arousals from sleep, apnea (cessation of

breathing), hypopnea (shallow breathing), hypoxia (low blood oxygen concentration), hypercapnia (high blood carbon dioxide level), loud snoring, and daytime sleepiness. Patients will present with complaints of snoring, excessive daytime sleepiness, and potentially other symptoms such as nocturnal choking, morning headaches, and fatigue.

Continuous positive airway pressure (CPAP) therapy, which delivers oxygen in a continuous stream independent of whether the patient is taking or exhaling a breath, is the first-line treatment for patients with moderate-to-severe OSA. However, despite its efficacy and many redesigns by manufacturers aimed at increasing patient comfort, patient adherence to CPAP therapy is low and has prompted the development of more tolerable devices for treatment of patients with OSA. Oral appliances may also be considered for less severe OSA or for CPAP intolerance, and invasive procedures can include tracheostomy, nasal reconstruction, uvulopalatopharyngoplasty, and tongue advancement or reduction.

The hypoglossal nerve stimulator (HNS) is an implanted medical device that works to reduce the occurrence of obstructive sleep apnea by electrically stimulating the hypoglossal nerve to the tongue. This stimulation activates the muscles of the tongue, increasing the tone and moving it forward, away from the back of the airway. The hypoglossal nerve stimulation system (HGNS) consists of 3 implanted components: a small implanted pulse generator (IPG), a respiratory-sensing lead, and a stimulating lead surgically placed on the HGN. The IPG is subcutaneously implanted beneath the clavicle in the upper chest and delivers HGNS via the stimulating lead. The sensing lead is placed in the intercostal space and contains a pressure sensor for detecting respiratory signals. The IPG synchronizes stimulation of the hypoglossal nerve with the patient's breathing cycle using input from the sensing lead. The device may be activated 4 to 6 weeks after surgical implantation and the stimulation is titrated to yield ideal outcomes coupled with minimal side effects for each patient. Titrations can occur several times over the months following implantation. The patient uses a remote control to turn the device on before going to sleep and turn it off upon awakening.

US Food and Drug Administration (FDA):

At the current time, FDA approved hypoglossal nerve neurostimulation devices include but are not limited to the Inspire II System, and the Inspire 3028 system for Upper Airway Stimulation (UAS) Therapy. The FDA classifies the Inspire Upper Airway Stimulation (UAS) system (Inspire Medical Systems Inc.) as a class III device, under the designation "Stimulator, Hypoglossal Nerve, Implanted, Apnea". The Inspire UAS was granted premarket approval (PMA) on April 30, 2014, and updated on June 23, 2017, by the Center for Devices and Radiological Health for the treatment of moderate-to-severe obstructive sleep apnea (OSA) (apnea-hypopnea index 15-65 events per hour) in adult patients at least 22 years of age who are intolerant or have confirmed failure of continuous positive airway pressure (CPAP) and who have an absence of complete concentric collapse at the level of the soft palate. In 2017, the FDA approved the Inspire Model 3028 device, which is smaller than the previous device, and carries magnetic resonance imaging (MRI) conditional labeling, indicating that patients with the model 3028 implanted may safely undergo MRI. ²

POSITION STATEMENT ³⁰

Hypoglossal nerve stimulation (HGNS) for the treatment of moderate-to-severe obstructive sleep apnea (OSA) is considered experimental, investigational and unproven in adult patients when continuous positive airway

pressure (CPAP) therapy or bi-level positive airway pressure (BPAP) machines) have failed to correct OSA.

Experimental, investigational and unproven status are based upon:

- Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
- Insufficient evidence to support improvement of the net health outcome, and
- Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives

LIMITATIONS³⁰

Implantable neurostimulator includes, but not limited to the HGNS, are considered experimental, investigational and unproven due to insufficient clinical evidence supporting the safety and efficacy for treating obstructive sleep apnea.

SUMMARY OF MEDICAL EVIDENCE³⁻²⁶

The overall quality of the evidence regarding the efficacy and safety of HGNS for treatment of OSA presented in the peer reviewed published studies is low. While the device has been approved by the US Food and Drug Administration and indicated for the treatment of moderate-to-severe obstructive sleep apnea (OSA), available evidence is insufficient to conclude the long-term safety and efficacy of the device. The study design (all studies were observational or pretest/posttest), substantial loss to follow-up, short term follow-up, small sample sizes, potential for selection bias, variations in AHI inclusion criteria, lack of intention-to-treat analyses and lack of missing data imputation limit conclusions of these devices. In summary, the evidence is insufficient to determine the effects of this technology on net health outcomes and there is insufficient evidence to show HGNS is reasonable and necessary for the treatment of OSA. Further large, randomized, comparative, controlled studies are needed to determine the safety and efficacy, define optimal patient selection and assess long-term effect of HGNS on OSA-related morbidity and mortality. The most relevant studies are outlined below.

The Stimulation Therapy for Apnea Reduction (STAR) trial was the primary study for the upper-airway stimulation device (Strollo et. al., 2014). This study evaluated the clinical safety and effectiveness of upper airway stimulation at 12 months for the treatment of moderate to severe obstructive sleep apnea (OSA). Using a multicenter, prospective, single-group, cohort design, an upper airway stimulation device was surgically implanted in patients with obstructive sleep apnea who had difficulty either accepting or adhering to CPAP therapy. The primary outcome measures were the apnea-hypopnea index (AHI; the number of apnea or hypopnea events per hour, with a score of ≥ 15 indicating moderate to severe apnea) and the oxygen desaturation index (ODI: the number of times per hour, with a score of ≥ 4 percentage points from baseline). Secondary outcome measures were the Epworth Sleepiness Scale, the Functional Outcomes of Sleep Questionnaire (FOSQ), and the percentage of sleep time with the oxygen saturation less than 90%. Consecutive participants with a response were included in a randomized, controlled therapy withdrawal trial. The study included 126 participants; 83% were men. The mean age was 54.5 years and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 28.4. The median AHI score at 12

months decreased 68% from 29.3 events per hour to 9.0 events per hour ($P < 0.001$); the ODI score decreased 70%, from 25.4 events per hour to 7.4 events per hour ($P < 0.001$). Secondary outcome measures showed a reduction in the effects of sleep apnea and improved quality of life. In the randomized phase, the mean AHI score did not differ significantly from the 12-month score in the nonrandomized phase among the 23 participants in the therapy maintenance group (8.9 and 7.2 events per hour, respectively) among the 23 participants in the therapy withdrawal group (25.8 vs. 7.6 events per hour, $P < 0.001$). The ODI results followed a similar pattern. The rate of procedure related serious adverse events was less than 2%. The authors concluded in this uncontrolled cohort study, upper-airway stimulation led to significant improvements in objective and subjective measurements of the severity of obstructive sleep apnea. This study was funded by Inspire Medical Systems; STAR Clinical Trials NCT01161420. The lack of control group limits the validity of the results of this study.²³

Woodson et. al (2014) assessed the efficacy and durability of the upper airway stimulation via the hypoglossal nerve on obstructive sleep apnea (OSA) severity including objective and subjective clinical outcome measures in a subgroup analysis of the STAR trial. The study included a consecutive cohort of 46 responders at 12 months from a prospective phase III trial of 126 implanted participants. Participants were randomized to either therapy maintenance (“ON”) group or therapy withdrawal (“OFF”) group for a minimum of 1 week. Short-term withdrawal effect as well as durability at 18 months of primary (apnea hypopnea index and oxygen desaturation index) and secondary measures (arousal index, oxygen desaturation metrics, Epworth Sleepiness Scale, Functional Outcomes of Sleep Questionnaire, snoring and blood pressure) were assessed. Both the therapy withdrawal group and the maintenance group demonstrated significant improvements in outcomes at 12 months compared to study baseline. In the randomized assessment, therapy withdrawal group returned to baseline, and therapy maintenance group demonstrated no change. At 18 months with therapy on in both groups, all objective respiratory and subjective outcomes measures showed sustained improvement similar to those observed at 12 months. The authors concluded that withdrawal of therapeutic upper airway stimulation results in worsening of both objective and subjective measures of sleep and breathing, which when resumed results in sustained effect at 18 months. The authors state that reduction of obstructive sleep apnea severity and improvement of quality of life were attributed directly to the effects of the electrical stimulation of the hypoglossal nerve. The author-reported limitations of this study to include selection bias of only including responders to upper airway stimulation therapy and the lack of subject or investigating blinding. This study was funded by Inspire Medical Systems.²⁴

In 2015, Strollo et. al. evaluated the stability of improvement in polysomnographic measures of sleep disordered breathing, patient reported outcomes, the durability of hypoglossal nerve recruitment and safety at 18 months in the Stimulation Treatment for Apnea Reduction (STAR) trial participants. Prospective multicenter single group trial with participants serving as their own controls. Primary outcome measures were the apnea-hypopnea index (AHI) and the 4% oxygen desaturation index (ODI). Secondary outcome measures were the Epworth Sleepiness Scale (ESS), the Functional Outcomes of Sleep Questionnaire (FOSQ), and oxygen saturation percent time $< 90\%$ during sleep. Stimulation level of each participant was collected at three predefined thresholds during awake testing. The median AHI was reduced by 67.4% from baseline of 29.3 to 9.7/h at 18 months. The median ODI was reduced by 67.5% from 25.4 to 8.6/h at 18 months. The FOSQ and ESS improved significantly at 18

months compared to baseline values. The functional threshold was unchanged from baseline at 18 months. Two participants experienced a serious device related adverse event requiring neurostimulator repositioning and fixation. No tongue weakness was reported at 18 months. The authors concluded upper airway stimulation via the hypoglossal nerve maintained a durable effect of improving airway stability during sleep and improved patient reported outcomes (Epworth Sleepiness Scale and Functional Outcomes of Sleep Questionnaire) without an increase of the stimulation thresholds or tongue injury at 18 months of follow-up. The limitations are the same as the original study, the lack of control group limits the validity of the results of this study. This study was funded by Inspire Medical Systems. ²²

Woodson et. al. (2018) conducted a multicenter prospective cohort study to describe the 5 year outcomes of hypoglossal cranial nerve upper airway stimulation for obstructive sleep apnea: the STAR trial. From a cohort of 126 patients, 97 completed protocol, and 71 consented to a voluntary polysomnogram. Those having continuous positive airway pressure failure with moderate to severe OSA, body mass index <32 kg/m², and no unfavorable collapse on drug-induced sleep endoscopy were enrolled in a phase 3 trial. Prospective outcomes included apnea-hypopnea index (AHI), oxygen desaturation index, and adverse events, as well as measures of sleepiness, quality of life, and snoring. Patients who did and did not complete the protocol differed in baseline AHI, oxygen desaturation index, and Functional Outcomes of Sleep Questionnaire scores but not in any other demographics or treatment response measures. Improvement in sleepiness (Epworth Sleepiness Scale) and quality of life was observed, with normalization of scores increasing from 33% to 78% and 15% to 67%, respectively. AHI response rate (AHI <20 events per hour and >50% reduction) was 75% (n = 71). When a last observation carried forward analysis was applied, the responder rate was 63% at 5 years. Serious device-related events all related to lead/device adjustments were reported in 6% of patients. The authors concluded, improvements in sleepiness, quality of life, and respiratory outcomes are observed with 5 years of upper airway stimulation (UAS). Serious adverse events are uncommon. Results reported that in a selected group of participants with moderate to severe OSA who are unable to accept or adhere to CPAP, hypoglossal nerve stimulation therapy can provide significant improvement in objective measures of sleep-disordered breathing and important sleep-related quality-of-life outcome measures. This study was funded by Inspire Medical Systems. ²⁶

A recent meta-analysis (Kompelli et al, 2018) of available HNS studies investigating treatment of OSA to analyze objective and subjective outcomes and side effects was conducted. Studies with objective and subjective endpoints in sleep were included for analysis. Adverse events from trials were also recorded. Across 16 studies, 381 patients were analyzed. At 6 months (p = 0.008), mean SAQLI improved by 3.1 (95%CI, 2.6-3.7). At 12 months (p < 0.0001), mean AHI was reduced by 21.1 (95%CI, 16.9-25.3), mean ODI was reduced by 15.0 (95%CI, 12.7-17.4), mean ESS was reduced by 5.0 (95%CI, 4.2-5.8), mean FOSQ improved by 3.1 (95%CI, 2.6-3.4). Pain (6.2%:0.7-16.6), tongue abrasion (11.0%:1.2-28.7), and internal (3.0%:0.3-8.4)/external device (5.8%:0.3-17.4) malfunction were common adverse events. The authors concluded that HNS is a safe and effective treatment for CPAP refractory OSA but that further study comparing HNS to other therapies is required. ¹⁶

Professional Society Guidelines ²⁷⁻²⁹

American Academy of Otolaryngology-Head and Neck Surgery: UAS via the hypoglossal nerve for the treatment of adult OSA syndrome is considered to be an effective second-line treatment of moderate to severe

OSA in patients who are intolerant or unable to achieve benefit with PAP. Not all adult patients are candidates for UAS therapy and appropriate polysomnographic, age, BMI and objective upper airway evaluation measures are required for proper patient selection.²⁸

American Academy of Sleep Medicine: Hypoglossal nerve stimulation is not addressed in the guidelines. The guideline on surgical treatment of OSA in adults is in the process of being updated.²⁷

National Institute of Health and Care Excellence (NICE): Current evidence on the safety and efficacy of hypoglossal nerve stimulation for moderate to severe obstructive sleep apnea is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.²⁹

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
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
64999	Unlisted procedure, nervous system

HCPCS	Description
	Any/All

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

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REVISION/REVIEW HISTORY

6/17/20: New Policy

6/9/21: Policy reviewed, no changes. Updated references.