Molina Clinical Policy
Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (OSA): Policy No. 363

Last Approval: 10/12/2022
Next Review Due By: October 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Obstructive Sleep Apnea (OSA) is a chronic disorder characterized by an intermittent cessation of breathing that occurs when the upper airway collapses during sleep. The repetitive complete or partial collapse of the oropharyngeal airway during sleep results in obstructive apneas, hypopneas, and/or respiratory effort-related arousals. Patients will present with complaints of snoring, excessive daytime sleepiness, and other symptoms such as nocturnal choking, morning headaches, and fatigue. Multiple comorbidities are associated with untreated OSA, including an increased risk of cardiovascular disease, arrhythmias, hypertension, and mortality. OSA is diagnosed based on the existence or absence of associated symptoms and the frequency of respiratory episodes during sleep (Mashaqi et al. 2021).

A positive airway pressure (PAP) machine is the first-line treatment for OSA. In general, the two types of PAP indicated in most OSA patients are continuous PAP (CPAP) and auto-adjusting PAP (APAP). CPAP is usually the first-line therapy option for most adult patients with moderate to severe OSA; however, a considerable proportion of patients are nonadherent to PAP due to low patient tolerance. Patients who do not prefer or do not respond to CPAP may benefit from oral appliances or surgery to repair anatomic structures of the upper airway. Oral appliance therapy is the primary non-surgical, non-CPAP treatment for individuals with OSA and may be considered for less severe OSA or CPAP intolerance. Oral appliances used to treat sleep-disordered breathing include mandibular advancement/retention devices, tongue retention devices, and soft palate lifters. Adults with OSA who do not respond or tolerate CPAP or oral appliances, or who have anatomical blockages, may be candidates for surgical therapy. Conventional surgical procedures, which can be quite invasive and range in success rates from 35 to 86% depending on the surgery, include septoplasty, nasal polypectomy, adenoidectomy, tonsillectomy, uvulopalatopharyngoplasty, uvuloplasty, glossectomy, tongue base reduction, mandibular advancement, genioglossal advancement, hyoid myotomy suspension, maxillomandibular advancement, tracheostomy, and bariatric surgery (Mashaqi et al. 2021). Upper airway stimulation (UAS) is a more recent surgical option for treating obstructive sleep apnea with a success rate of about 75% at 5 years (Woodson et al. 2018).

Hypoglossal nerve stimulation (HGNS), or UAS, is a novel therapy in treating moderate-to-severe OSA and is a second-line therapy for those patients who have failed PAP. The implantable HNS device lowers the occurrence of OSA by electrically stimulating the hypoglossal nerve to the tongue. The stimulation activates the tongue muscles, raising the tone and pulling it forward, away from the back of the airway. The HGNS system consists of three implantable components: 1) a stimulation lead that delivers mild stimulation to maintain multilevel airway patency during sleep, 2) a breathing sensor lead that detects breathing patterns, and 3) a generator that monitors breathing patterns. The two external components are a patient sleep remote for noninvasively activating the generator and a physician programmer for noninvasively interrogating and configuring the generator settings. The implantable components have a battery life of 7 to 10 years.

This policy addresses FDA approved HGNS devices for the treatment of moderate-to-severe OSA.

Regulatory Status

Currently, the only commercially available HGNS system available in the U.S. (Inspire Medical, Minneapolis, MN): Inspire II System and the Inspire 3028 system for UAS Therapy. The Inspire UAS system is classified as a **Class III device** by the FDA as "Stimulator, Hypoglossal Nerve, Implanted, Apnea." Search MNQ in the Product Code field in the Premarket Approval Database.

The Inspire UAS was granted premarket approval in April 2014 and updated in June 2017 for the treatment of moderate-to-severe OSA (AHI 15-65 events per hour) in adult patients at least 22 years of age who are intolerant or have confirmed failure of CPAP and who have an absence of complete concentric collapse at the level of the soft palate. (P130008 S021).

The FDA authorized the Inspire Model 3028 device in 2017, which is smaller than the prior device and has conditional labeling for MRI, indicating that patients who have the model 3028 implanted may do so safely.

COVERAGE POLICY

HGNS for the treatment of moderate-to-severe OSA **is considered medically necessary** when **ALL** of the following are met:

1. Member is 22 years of age or older; **AND**
2. Body mass index (BMI) is less than 35 kg/m^2; **AND**
3. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; **AND**
4. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total Apnea Hypopnea Index (AHI); **AND**
5. AHI is 15 to 65 events per hour; **AND**
6. Documentation of ONE of the following:
   a. CPAP failure (defined as AHI greater than 15 despite CPAP usage); or
   b. CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned) including shared decision making that the Member was intolerant of CPAP despite consultation with a sleep expert;

AND

7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; **AND**
8. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale); **AND**
9. The device is FDA approved.

Limitations and Exclusions

HGNS **is considered experimental, investigational, and unproven** for the following:
1. All any indication not listed above.
2. Non-FDA-approved treatments due to insufficient evidence of being safe and effective.

HGNS **is considered** a **contraindication/exclusion** for the following:
1. Central and mixed apneas that make up more than one-quarter of the total AHI
2. Implantable device could experience unintended interaction with the HGNS implant system
3. BMI equal to or greater than 35

4. Neuromuscular disease
5. Hypoglossal-nerve palsy
6. Severe restrictive or obstructive pulmonary disease
7. Moderate-to-severe pulmonary arterial hypertension
8. Severe valvular heart disease
9. New York Heart Association class III or IV heart failure
10. Recent myocardial infarction or severe cardiac arrhythmias (within the past 6 months)
11. Persistent uncontrolled hypertension despite medication use
12. An active, serious mental illness that reduces the ability to carry out Activities of Daily Living (ADLs) and would interfere with the Member's ability to operate the HNS and report problems to the attending provider.
13. Coexisting non-respiratory sleep disorders that would confound functional sleep assessment
14. Members who are, or who plan to, become pregnant.
15. Members requiring MRI with model 3024.
16. Members requiring MRI with model 3028 can undergo MRI on the head and extremities if certain conditions and precautions are met. (Please refer to the *Manufacturer Guidelines* for this model [and future models] for more information).
17. Unable or do not have the necessary assistance to operate the sleep remote.
18. Any condition or procedure that has compromised neurological control of the upper airway.

Additional Documentation Requirements

1. **Drug Induced Sleep Endoscopy (DISE).** Due to documented inconsistency in determining if complete concentric collapse (CCC) is present, the inserting Provider shall be certified by the FDA approved manufacturer's second opinion service of validation via video clip submissions of at least 80% agreement in at least 15 consecutive studies. Inserting Providers shall submit documentation, if necessary.

2. **Shared Decision Making (SDM).** SDM shall be documented in the Member's record by the referring physician and the implanting physician. Both shall provide these documents if requested by this contractor.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

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 according to an updated Health Technology Assessment. HGNS for OSA is supported by a moderate body of consistent, low-quality evidence consisting of a number of smaller observational studies with limitations that may influence the interpretation of the overall quality of the evidence such as study design (all studies were observational or pretest/posttest) and variations in AHI inclusion criteria. While the device has been approved by the FDA and indicated for the treatment of moderate-to-severe OSA, the evidence is insufficient to determine the effects of this technology on net health outcomes. 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 (Hayes 2021).

Stimulation Therapy for Apnea Reduction (STAR)

The STAR trial was a multicenter prospective RCT study that used HNS (Inspire HNS device) that evaluated the safety and effectiveness for the treatment of moderate to severe OSA in 126 OSA patients (n=126) with difficulty initiating or maintaining CPAP therapy (Strollo et al. 2014). The oxygen desaturation index (ODI) decreased from 25.4 to 7.4 events per hour and the AHI from 29.3 to 9 events per hour at 12 months after HNS. Approximately 66% of participants had a favorable outcome (defined as a reduction of at least 50% and an AHI to below 20 events per hour). The reduction

in AHI was accompanied by enhancements in daytime drowsiness and functional sleep outcomes. Subjective measures, such as the Epworth Sleepiness Scale (ESS) and the Functional Outcomes of Sleep Questionnaire (FOSQ), demonstrated clinically significant improvement compared to baseline. Serious adverse events occurred at a rate of less than 2%. Withdrawal from randomized therapy revealed recurrence of symptoms and at least moderate OSA evidence. 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 OSA. The lack of control group limits the validity of the results of this study (STAR Clinical Trials NCT01161420; funded by Inspire Medical Systems).

Longer-term follow-up at 18-, 24-, 36-, 48-, and 60-months indicates that the benefit is durable if patients adhere to therapy (Dedhia et al. 2015; Soose et al 2016; Woodson et al. 2016; Gillespie et al. 2017; Woodson et al. 2018).

STAR Trial 18-Month Follow-Up

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 were evaluated in the STAR trial participants. Prospective multicenter single group trial with participants serving as their own controls. Primary outcome measures were the AHI and the 4% ODI. Secondary outcome measures were the ESS, the 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 UAS via the hypoglossal nerve maintained a durable effect of improving airway stability during sleep and improved patient reported outcomes (ESS and FOSQ) 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.

STAR Trial 5-Year Outcomes

Woodson, et al. (2018) conducted a multicenter prospective cohort study to describe the 5-year outcomes of the STAR Trial from the cohort of 126 patients, of which 97 completed protocol and 71 consented to a voluntary PSG. Improvement in sleepiness (ESS) and quality of life was observed, with normalization of scores increasing from 33% to 78% and 15% to 67%, respectively. AHI response rate (AHI less than 20 events per hour and greater than 50% reduction) was 75% (n equal to 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 that there were improvements in sleepiness, quality of life, and respiratory outcomes are observed with 5 years of UAS. Serious adverse events are uncommon. UAS is a nonanatomic surgical treatment with long-term benefit for individuals with moderate to severe OSA who have failed nasal CPAP.

The ADHERE (Adherence and Result of Upper Airway Stimulation for OSA International Registry) registry was established to collect demographic, surgical outcome, complications, quality of life, and patient-reported outcomes from patients receiving UAS treatment in the U.S. and Europe. The post-approval registry reported that from baseline to last visit at 12-month postimplant, the median AHI was reduced from 34 to 7 occurrences, and the median Epworth drowsiness rating was lowered from 12 to 7. In post-hoc analysis, each 1-year increase in age increased the probability of treatment success by 4%. Each unit rise in BMI reduced the likelihood of treatment success by 9%. Age remained a statistically significant predictor of treatment effectiveness in the multivariable model. According to the authors, UAS is an effective therapy option with high patient satisfaction and few side occurrences. Treatment response is predicted by increasing age and decreasing BMI (Suurna et al. 2021).

Kompelli et al. (2018) conducted a meta-analysis of available HNS trials to evaluate the objective and subjective results and adverse effects of treated OSA. After a thorough search of PubMed and Scopus, 16 case series containing the study of 381 patients were located. At 6 months, the average Sleep Apnea Quality of Life Index (SAQLI) improved by 3.1 (95% confidence interval [CI], 2.6-3.7). At 12 months, the mean AHI had decreased by 21.1 (95%CI, 16.9-25.3), the mean ODI had decreased by 15.0 (95%CI, 12.7-17.4), the mean ESS had decreased by 5.0 (95%CI, 4.2-5.8), and the mean FOSQ improved by 3.1 (95%CI, 2.6-3.4). Among the unanticipated outcomes of the study were pain, tongue

abrasion, and internal/external device malfunctions. The authors concluded that HNS is a safe and effective treatment for CPAP-resistant OSA; however, further study comparing HNS to other therapies is required.

Costantino et al. (2019) performed a systematic review and meta-analysis to assess the clinical outcomes of HNS in the treatment of moderate to severe OSA. This review omitted duplicate cohorts of identical studies with varying follow-up durations (STAR Trial) and the German Post-Market Study. A total of 350 patients from 12 studies were included in the study (median age 54.3 years, median BMI 29.8). All primary outcomes, according to the authors, demonstrated a considerable improvement. HNS has reduced AHI by 56.2% (Inspire), 53.5% (ImThera), and 44.3% (Apnex) at 12 months and 59.2% (Inspire) at 60 months, respectively, with a surgical success rate of 72.4% (Inspire), 76.9% (ImThera), and 55%(Apnex) at 12 months and 75% (Inspire) at 60 months. At 12 months, the ODI showed a reduction of 53.4% (Inspire), 47.6% (ImThera), and 24.9% (Apnex), respectively, and 63.6% (Inspire) at 60 months. Self-reported outcome measurements also showed a similar pattern, with ESS mean reductions of 5.27 (Inspire), 2.90 (ImThera), and 4.20 (Apnex) at 12 months and 4.40 (Inspire) after 60 months, respectively. The data show that the optimal clinical improvement obtained at the 12-month follow-up is maintained after 5 years. HNS has been shown to be a safe surgical procedure with a low rate of serious adverse events such as permanent impairment, life-threatening illness, or new or prolonged hospitalization with serious health impairment. After 5 years, 6% of patients required surgical repositioning or replacement of the neurostimulator or implanted leads. The authors reported that the STAR trial is the only prospective patient cohort with a follow-up longer than 12 months, with only 57% (n=71) of the STAR trial cohort completing the 5-year polysomnographic study. All of the studies included were prospective single-arm cohort studies.

National and Specialty Organizations

The **American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS),** In a 2021 position statement supported HGNS as an effective second-line treatment of moderate-to-severe OSA.

The AAO-HNS considers UAS via the hypoglossal nerve for the treatment of adult OSA syndrome to be a safe and effective second-line treatment for patients with moderate to severe OSA and intolerant or unable to achieve benefit with positive pressure therapy (revised November 2019).

The **American Academy of Sleep Medicine (AASM)** Clinical Practice Guideline for Diagnostic Testing for Adult OSA states that the third edition of the International Classification of Sleep Disorders (ICSD-3) defines OSA as a PSG-determined obstructive respiratory disturbance index (RDI) greater than or equal to 5 events/hour associated with the typical symptoms of OSA (e.g., unrefreshing sleep, daytime sleepiness, fatigue or insomnia, awakening with a gasping or choking sensation, loud snoring, or witnessed apneas), or an obstructive RDI greater than or equal to 15 events/hour (even in the absence of symptoms) (Kapur 2017).

The **National Institute of Health and Care Excellence (NICE)** (2017) in an interventional procedure guidance (IPG598) concluded “Current evidence on the safety and efficacy of hypoglossal nerve stimulation for moderate to severe OSA is limited in quantity and quality. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research.”

SUPPLEMENTAL INFORMATION

Apnea Hypopnea Index (AHI): The number of Apneas plus the number of Hypopneas during the entire sleeping period, times 60, divided by total sleep time in minutes; unit: event per hour (AASM Scoring Manual, 2020).

The hypoglossal nerve (cranial nerve XII) innervates the genioglossus muscle. Stimulation of the nerve causes anterior movement and stiffening of the tongue and dilation of the pharynx. HGNS reduces airway collapsibility and alleviates obstruction at both the level of the soft palate and tongue base.

Drug-induced sleep endoscopy (DISE) replicates sleep with an infusion of propofol. DISE will suggest either a flat, anterior-posterior collapse or complete circumferential oropharyngeal collapse. Concentric collapse decreases the success of HGNS and is an exclusion criterion from the FDA.

CODING & BILLING INFORMATION

CPT Codes

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
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64999	Unlisted procedure, nervous system

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2022 Policy revised. Updated summary of medical evidence and references. IRO Peer Review. Sep 2022. Practicing Physician. Board certified in Sleep Medicine. Notable revisions to coverage criteria include:
- Addition of criterion: 'The device is FDA approved and insertion is performed by a qualified physician (MD or DO) who is a board-certified, or a board-eligible otolaryngologist.'
- DISE and SDM criteria moved from 'Exclusions and Limitations' section to 'Additional Required Documentation' section at the end of 'Coverage Policy' criteria section.
- Revised verbiage for clarification of criteria

10/13/2021 Policy revised. Criteria updated to align with CMS LCDs (see Reference no. 1). Added CPT 64568 and updated references. IRO Peer Review. 9/24/2021. Practicing physician. Board-certified in Sleep Medicine.

6/9/2021 Policy reviewed, no changes, updated references.

6/17/2020 New policy. IRO Peer Review. April 2020. Practicing physician. Board-certified in Sleep Medicine.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*