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

Last Approval: 6/12/2024
Next Review Due By: June 2025

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 (Kline 2023; Malhotra & Kundel 2024).

Positive airway pressure (PAP) therapy is the first-line treatment for OSA. A considerable proportion of patients are nonadherent to PAP due to low patient tolerance. Patients who do not prefer or do not respond to PAP therapy may benefit from oral appliances or surgery to repair anatomic structures of the upper airway. 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 (Kline 2023; Malhotra & Kundel 2024).

Hypoglossal nerve stimulation (HGNS), or upper airway stimulation (UAS), is a novel therapy for treating moderate-to-severe OSA and is a second-line therapy for those patients who have failed PAP therapy. The implantable HGNS 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 (Suurna 2024).

Pediatric sleep-disordered breathing is a term that describes nocturnal breathing abnormalities specific to pediatric patients. Pediatric sleep-disordered breathing encompasses habitual snoring to OSA and may include obstructive and non-obstructive causes of sleep-disordered breathing. Obstructive forms of sleep-disordered breathing are common in the pediatric population with peak incidence between 2 and 8 years of age. Pediatric populations at high-risk of sleep-disordered breathing include children with obesity, congenital syndromes, craniofacial abnormalities, and neuromuscular disorders. Management of sleep-disordered breathing and OSA in pediatric patients follows the same pathways as adult patients. An adenotonsillectomy is typically the first-line therapy in children with moderate-to-severe OSA who are otherwise healthy (Kirkham 2024; Paruthi 2024).

Children with Down syndrome typically have multiple airway abnormalities contributing to their OSA. These abnormalities include soft tissue and skeletal alterations that lead to upper airway obstruction. Due to these

abnormalities, sleep-disordered breathing prevalence in pediatric patients with Down syndrome is estimated to be 30-100%. Children with Down syndrome often have persistent OSA despite undergoing adenotonsillectomy and typically continue to require PAP therapy. The success rate of adenotonsillectomies in children with Down syndrome is estimated to only be as high as 33%. HGNS is a treatment option for children with Down syndrome "who are not able to benefit from other upper airway surgeries or [PAP therapy]" (Kirkham 2024; Ostermaier 2022).

Regulatory Status

Currently, the only HGNS systems available with U.S. Food and Drug Administration (FDA) approval in the U.S. are the Inspire II System and the Inspire 3028 system for UAS Therapy (Inspire Medical, Minneapolis, MN). The Inspire devices are classified as **Class III devices** by the FDA. 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: 1) at least 22 years of age who are intolerant of or have confirmed failure of PAP therapy, 2) have an absence of complete concentric collapse at the level of the soft palate, and 3) a body mass index (BMI) ≤ 32 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.

In March 2023, the FDA approved the use of the Inspire UAS for the treatment of OSA in pediatric Down syndrome patients between the ages of 13 and 18 years with severe OSA who 1) do not have complete concentric collapse at the soft palate level, 2) are contraindicated for or are not effectively treated by adenotonsillectomy, 3) have been confirmed to fail or cannot tolerate PAP therapy despite attempts to improve compliance, and 4) have followed standard of care in considering all other alternative or adjunct therapies ([1]FDA 2023). The Inspire UAS was granted expanded FDA approval in June 2023 for use in all adult patients with a BMI ≤ 40 and an AHI 15-100 events per hour ([2]FDA 2023). FDA approval was also granted for adult patients 18-21 years of age and either have a contraindication for an adenotonsillectomy or have not been effectively treated for OSA with an adenotonsillectomy ([2]FDA 2023).

The safety and efficacy of the aura6000 System (LivaNova PLC – device previously marketed by ImThera Medical, Inc.) is currently being assessed in a clinical study (NCT04950894) scheduled to conclude in July 2024 (ClinicalTrials.gov 2023). An additional randomized controlled trial (NCT02263859) has been completed with published data (ClinicalTrials.gov 2024). However, the aura6000 System **has not** received FDA approval as of June 2024. Search product code "MNQ" in the FDA Premarket Approval Database for current FDA approvals for HGNS devices for the treatment of OSA.

COVERAGE POLICY

Hypoglossal Nerve Stimulation (HGNS) for the treatment of moderate-to-severe obstructive sleep apnea (OSA) in adult members **is considered medically necessary** when **ALL** of the following are met:

1. **ONE** of the following:
   a. Age is 18-21 years and an adenotonsillectomy is contraindicated or has been ineffective
   b. Age is 22 years or older

2. Body mass index (BMI) is ≤ 40 kg/m^2

3. A polysomnography is performed within 24 months of first consultation for HGNS implant

4. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total Apnea Hypopnea Index (AHI)

5. AHI is 15 to 100 events per hour

6. Documentation of **ONE** of the following:
   a. PAP therapy failure (defined as AHI greater than 15 despite PAP usage)
   b. PAP therapy intolerance (defined as less than 4 hours per night, 5 nights per week or the PAP device has been returned) including shared decision making that the Member was intolerant of PAP therapy despite

consultation with a sleep expert

7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy procedure

8. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale)

9. The device is FDA approved

HGNS for the treatment of severe OSA in pediatric Members **is considered medically necessary** when **ALL** of the following are met:

1. Member is 13 to 18 years of age

2. Member has Down syndrome

3. AHI is ≥ 10 and ≤ 50 events per hour

4. Member has a BMI ≤ the 95th percentile based on age

5. Member has contraindication for or has not been effectively treated by adenotonsillectomy

6. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy procedure

7. Documentation of **ONE** of the following:
    a. PAP therapy failure (defined as AHI greater than 15 despite PAP usage)
    b. PAP therapy intolerance (defined as less than 4 hours per night, 5 nights per week or the PAP device has been returned) including shared decision making that the Member was intolerant of PAP therapy despite consultation with a sleep expert

Limitations and Exclusions

HGNS **is considered contraindicated/excluded** for the following:
1. Central and mixed apneas that make up more than 25% of the total AHI
2. An implantable device that could experience unintended interaction with the HGNS system
3. Body mass index > 40
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 and would interfere with the Member's ability to operate the HGNS 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 who require anticipated MRI with a noncompatible device. 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
16. Unable or do not have the necessary assistance to operate the sleep remote
17. Any condition or procedure that results in compromised neurological control of the upper airway

Additional Documentation Requirements

1. **Drug-Induced Sleep Endoscopy:** Due to documented inconsistency in determining if complete concentric collapse 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:** Shared decision making shall be documented in the Member's record by the referring physician and the implanting physician. Both physicians shall provide these documents if requested.

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 is supported by a moderate body of evidence. Initial FDA approval was based on outcomes reported in the Stimulation Therapy for Apnea Reduction (STAR) trial (Strollo et al. 2014). Additional FDA approvals for expanded indications have been granted as further studies have been published that have established the safety and efficacy of HGNS for additional indications, including the most recent expanded coverage for BMI and AHI based on Adherence and Result of Upper Airway Stimulation for OSA (ADHERE) registry data (Bosschieter et al. 2022). Long-term follow-up suggests that therapy benefit is durable if patients adhere to therapy (Bosschieter et al. 2022; Woodson et al. 2018). Adherence has been noted to decrease as time since device implantation increases; however, HGNS therapy adherence remains higher than PAP therapy adherence despite this noted decrease in adherence (Bosschieter et al. 2022).

Stimulation Therapy for Apnea Reduction (STAR) Trial

Strollo et al. (2014) completed the STAR trial, a multicenter prospective randomized controlled trial, that evaluated the safety and effectiveness of the Inspire HGNS device for the treatment of moderate-to-severe OSA in 126 OSA patients with difficulty initiating or maintaining PAP therapy. 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 HGNS. 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 limited the validity of the results of this study. This study was also funded by Inspire Medical Systems.

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 polysomnogram. 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 =71). When the 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.

Adherence and Result of Upper Airway Stimulation for OSA (ADHERE) International Registry

The ADHERE 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 (Heiser et al. 2019; Suurna 2021).

Bosschieter et al. (2022) analyzed available data in the ADHERE registry to determine if the efficacy of UAS therapy is influenced by preoperative OSA severity. Secondary outcomes measured included self-reported therapy efficacy, adherence, and patient-reported outcomes. Data from adult patients was "included if they had undergone UAS implantation and had at least 1 follow-up visit recorded in the database on June 8, 2021." The analysis included a total of 1963 patients out of the 2824 patients enrolled in the database. Patients were divided into five subgroups based on AHI for analysis: 1) AHI 0-15 (n=42), 2) AHI 16-29 (n=765), 3) AHI 30-50 (n=821), 4) AHI 51-65 (n=258), and 5) AHI > 65 (n=77). The average AHI across all subgroups was 33.0 events/hour at baseline, 7.8 events/hour at 6-months, and 10.2 events/hour at 12-months. The average change in AHI across all subgroups was 23.0±18.3 events/hour at 6-months and 20.7±18.4 events/hour at 12-months. Subgroup 1 had the lowest average AHI (baseline = 11.2, 6-months = 6.1, 12-months = 7.8) and the lowest change in AHI (6-months = 0.28±10.19, 12-months = 2.57±7.9) across all follow-up points and subgroup 5 had the highest average AHI (baseline = 72.4, 6-months = 17.9, 12-months = 15.5) and the highest change in AHI (6-months = 50.3±24.8, 12-months = 56.0±21.1). The average BMI across all subgroups was 29.2±3.8 kg/m^2 with subgroup 1 having the lowest BMI (28.4±3.5 kg/m^2) and subgroup 5 having the highest BMI (30.6±3.6 kg/m^2). Therapy adherence decreased from baseline to 12-months across all subgroups. Subgroup 5 was noted to have the lowest adherence at 12-months (n=4.7 hours per night). However, researchers noted adherence to UAS therapy was still higher than the 4 hours per night cited for PAP therapy adherence. Efficacy was defined as "a 50% decrease in AHI and treatment AHI ≤ 20 events/hour." The efficacy for a 50% decrease in AHI was 42.1% for subgroup 1, 68.3% for subgroup 2, 68.5% for subgroup 3, 79.2% for subgroup 4, and 78.8% for subgroup 5. The efficacy for treatment AHI ≤ 20 events/hour was 94.7% for subgroup 1, 85.0% for subgroup 2, 71.0% for subgroup 3, 65.4% for subgroup 4, and 66.7% for subgroup 5. The authors concluded that UAS therapy is safe and effective for the treatment of moderate-to-severe OSA regardless of the severity of OSA based on AHI.

Meta-Analyses and Systematic Reviews

Kim et al. (2024) completed a systematic review and meta-analysis to determine the efficacy of HGNS in treating OSA. A total of 44 studies were included with a total of 8670 patients. The pooled outcomes used to determine efficacy included AHI, ODI, ESS, FOSQ, lowest oxygen saturation, and time under 90% oxygen saturation (T90), Efficacy was assessed at 12-months, 24-months, and 36-months. Overall, HGNS significantly reduced AHI, ODI, and T90 at 12-months post-implantation. An improvement in lowest oxygen saturation was also noted at 12-months. Reductions in AHI, ODI, T90, and ESS continued up to 36-months post-implantation with improvements also noted in the FOSQ at 36-months. Subgroup analysis based on follow-up timing (3-months and 12-months) also demonstrated similar improvements in all outcome measures; however, efficacy was significantly reduced at 12-months when compared to 3-months, indicating that efficacy decreases over time. When comparing 12-, 18-, 24-, and 36-month follow-up periods, no significant differences were noted in the improvement of AHI; however, ESS, FOSQ, ODI, and T90 "demonstrated that HGNS was effective, regardless of follow-up timing." Clinical improvement was measured as "the reported rates of AHI < 5, < 10, and < 15" and were 47%, 72%, and 82%, respectively at 12-months. The Sher criteria was used to determined success rate and was reported as 80% at 12-months. Clinical improvement at the 36-month follow-up period was reported as AHI < 5 and < 15 and was 34% and 74%, respectively. The Sher criteria reported success rate was 73% at 36-months. Tongue abrasion was the only adverse effect measured and was 9% across all studies. Researchers concluded "that HGNS is an effective treatment option for the management of OSA…[and] can

significantly improve objective and subjective clinical outcomes." Efficacy was noted to gradually decrease until 12 months after implantation and then remain consistent between 12- and 36-months.

Costantino et al. (2020) performed a systematic review and meta-analysis to assess the clinical outcomes of HGNS 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. HGNS 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. HGNS 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.

HGNS for Pediatric Down Syndrome Patients

Liu et al. (2022) completed a systematic review and meta-analysis to evaluate the efficacy and adverse effects of HGNS in adolescents with Down Syndrome and OSA. The study included 9 articles with a total of 106 patients between the ages of 10 and 21 years. The pooled AHI was significantly lower in patients following placement of the Inspire HGNS. There was a mean reduction of 17.43 events per hour between all included studies. The most common complication was pain or discomfort in the tongue or mouth. Follow-up periods varied between the included studies, with one study having a follow-up duration longer than one year. In terms of serious adverse events, 7 (10.1%) patients required readmission, 4 (5.9%) required reoperation, and 1 (1.5%) developed a pressure ulcer.

Yu et al. (2022) completed a multicenter, single-group cohort study that included 42 adolescents between the ages of 10 and 21 years with Down syndrome. Persistent severe OSA was defined as an AHI ≥ 10 events per hour following adenotonsillectomy and either the inability to tolerate PAP therapy or nighttime tracheostomy dependence. There was a 1-year post-operation follow-up period with polysomnogram, and quality of life outcomes assessed at 1, 2, 6, and 12-months. Subjective caregiver-reported outcomes were obtained as a secondary outcome using the OSA-18 and modified-ESS surveys at baseline before operation and then at 2, 6, and 12-months post-operation. Exclusion criteria included central apnea contribution over 25%, a BMI over the 95th percentile on the CDC neurotypical growth curve, a medical condition that would require future MRI testing, DISE findings consistent with complete concentric collapse, or an AHI of ≥ 50 events per hour. Most patients were able to be discharged on post-operation day 1 with only one patient requiring a 3-night observation due to a concurrent upper respiratory infection. The most common complication reported was tongue or oral discomfort or pain. There were 4 device- or surgery-related hospital readmissions as a result of device extrusion due to the patient picking at the submental incision, a surgical site infection at the chest incision exacerbated by the patient picking at the site, poorly controlled post-operative pain, and discomfort from sensing the stimulation in the jaw and chest. A pressure ulcer was reported due to extended position during surgery; however, the pressure ulcer resolved without intervention. The 12-month outcomes showed a mean decrease in AHI of 12.9 events per hour (a 51.2% decrease from baseline) and 27 of 41 patients were classified as therapy responders represented by at least a 50% post-operative decrease in AHI. The 12-month polysomnogram results were also promising with 30 out of 41 patients having an AHI < 10 events per hour, 14 out of 41 patients having an AHI < 5 events per hour, and 3 out of 41 patients having an AHI < 2 events per hour. One patient had a tracheostomy for OSA at baseline and that patient was able to be decannulated following UAS insertion. Limitations of this study were the absence of a control group, not all 12-month polysomnograms were full-night studies at a single voltage level, and there was site variation in sleep study reports.

National and Specialty Organizations

An international consensus statement on OSA was published in 2023 by 130 authors from OSA specialties including neurology, pulmonology, sleep medicine, otolaryngology, oral-maxillofacial surgery, dentistry, anesthesiology,

psychiatry, cardiology, and sleep physiology. The committee recommended HGNS for select patients with moderate-to-severe OSA that meet clinical criteria. The committee also recommended post-operation follow-up with a full-night polysomnogram (Chang et al. 2023).

The **American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)** published a 2023 consensus statement that recommended HGNS as a safe and effective treatment for severe persistent OSA in adolescents with Down syndrome (Ishman et al. 2023).

The AAO-HNS supported HGNS as an effective second-line treatment of moderate-to-severe OSA in adults in a 2021 position statement.
The AAO-HNS considers UAS via the hypoglossal nerve for the treatment of adult OSA to be a safe and effective second-line treatment for patients with moderate-to-severe OSA and intolerant or unable to achieve benefit with PAP therapy (AAO-HNS 2021).

The **German Society of Oto-Rhino-Laryngology, Head and Neck Surgery** released an updated position paper in 2022 supporting the use of a HGNS as a second-line treatment for moderate-to-severe OSA (Steffen et al. 2022).

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. AHI is measured in “events per hour” (AASM 2023).

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 per the FDA.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

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

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

06/12/2024	Policy reviewed, changes to criteria include age 18-21 years and adenotonsillectomy is contraindicated or has been ineffective, AHI ≤ 100, and BMI ≤ 40 for adult members. IRO Peer Review on April 15, 2024, by a practicing, board-certified physician with a specialty in Otolaryngology - Head and Neck Surgery.
06/14/2023	Policy revised. Updated coverage criteria to include indications for eligible pediatric patients with Down syndrome. Updated Overview, Summary of Medical Evidence, and References to include additional information specific to pediatric populations.

	Coding and billing updated to include codes 61886 and 68188. Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. Policy reviewed on May 9, 2023, by a practicing, board-certified physician in the areas of Otolaryngology – Head and Neck Surgery.
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.' • Drug-Induced Sleep Endoscopy and Shared Decision Making 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.
06/09/2021	Policy reviewed, no changes, updated references.
06/17/2020	New policy. IRO Peer Review. April 2020. Practicing physician. Board-certified in Sleep Medicine.

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