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

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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 intermittent cessation of or reduction in breathing due to upper airway collapses during sleep, leading to oxygen desaturation and sleep fragmentation. 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, cardiac arrhythmias, hypertension, and mortality. OSA is diagnosed based on the presence or absence of associated symptoms and the frequency of respiratory events during sleep.

Positive airway pressure (PAP) therapy is the first-line treatment for OSA, and a significant proportion of patients have difficulty adhering to the therapy. Patients who do not tolerate or respond to PAP therapy may benefit from oral appliances or surgery to modify the upper airway structure. Surgical interventions for OSA range from common surgeries like adenotonsillectomy and uvulopalatopharyngoplasty, to more invasive options like maxillomandibular advancement and tongue base reduction, with success rates varying by procedure (Kline 2025; Malhotra & Kundel 2025).

OSA is common in children with Down syndrome due to airway abnormalities, including soft tissue and skeletal differences that contribute to upper airway obstruction, with prevalence estimates ranging from 30 to 100%. While adenotonsillectomy is typically the first-line treatment, residual OSA can persist in up to 67% of cases. PAP therapy is the primary post-surgical treatment, but adherence challenges are common (Kirkham 2025; Ostermaier 2025).

Hypoglossal nerve stimulation (HGNS), also known as upper airway stimulation, is a novel second-line therapy for moderate-to-severe OSA in patients who have failed PAP therapy. HGNS devices aim to reduce OSA events by electrically stimulating the hypoglossal nerve, which activates muscles to increase tone and move the tongue forward, helping to prevent airway obstruction. An HGNS system consists of three implantable components: a stimulation lead that delivers mild electrical impulses to maintain multilevel airway patency during sleep, a sensor that detects breathing patterns, and a generator that processes sensor input and delivers stimulation as needed. Two external components include a patient sleep remote for noninvasive activation of the generator, and a physician programmer for configuring, monitoring, and adjusting device settings. The implantable components have a battery life of 7 to 10 years (Suurna 2025).

Regulatory Status

The *Inspire Upper Airway Stimulator (UAS)* system by Inspire Medical Systems was the first FDA-approved HGNS device for OSA, with original approval in 2014 and subsequent expanded labeling. In 2023, the FDA expanded approval to include adults aged 22 years and older, individuals aged 18-21 years with moderate-to-severe OSA, and pediatric patients aged 13-18 years with Down syndrome and severe OSA (AHI 10-50). Inspire's current MRI conditions apply to device-specific labeling, including MRI-conditional use for the Model 3028 system.

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In August 2025, the FDA approved the Nyxoah Genio® System 2.1, making it the second HGNS device available in the U.S. market. Genio is indicated for adult patients aged 22 years and older with moderate-to-severe OSA (AHI 15–65) who have failed, cannot tolerate, or are ineligible for standard-of-care treatments including lifestyle modification, positive airway pressure (PAP), oral appliance therapy, and relevant pharmacotherapy. Genio is a bilateral, leadless, battery-free system and is compatible with 1.5T and 3T MRI.

Other HGNS devices, including the aura6000 System by LivaNova, are currently undergoing PMA review but have not yet been approved by the FDA. HGNS devices are regulated as Class III implantable neurostimulation devices and can be searched in the PMA database under product code MNQ.

COVERAGE POLICY

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

1. Member is requesting ONE of the following devices and meets ALL device specific requirements:
   a. Inspire
      i. Age is 18-21 years and an adenotonsillectomy is contraindicated or has been ineffective OR age is 22 years or older
      ii. AHI is 15 to 100 events per hour
   b. Genio System
      i. Age is 22 years or older
      ii. AHI is 15 to 65 events per hour

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. Documentation of ONE of the following pertaining to Member's intolerance or failure of positive airway pressure (PAP) therapy despite consultation with a sleep expert:
   a. PAP therapy failure (defined as AHI > 15 despite PAP usage)
   b. PAP device return or therapy intolerance (defined as inability to use PAP ≥ 5 nights per week, with less than 4 hours of use per night)

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

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

HGNS with Inspire for the treatment of severe OSA in **PEDIATRIC** Members may be **considered medically necessary** when ALL the following are met:

1. Member is 13 to 18 years of age

2. Member has Down syndrome (i.e., Trisomy 21)

3. AHI is 10 - 50 events per hour

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

5. Member is contraindicated 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 pertaining to Member's intolerance or failure of positive airway pressure (PAP) therapy despite consultation with a sleep expert:
   a. PAP therapy failure (defined as AHI > 15 despite PAP usage)
   b. PAP device return or therapy intolerance (defined as inability to use PAP > 5 nights per week, with less than 4 hours of use per night)

Limitations and Exclusions

HGNS **is considered contraindicated/excluded** for ANY of following:

1. Existence of an implantable device that may be susceptible to unintended interaction with the HGNS system
2. Any condition or procedure that results in compromised neurological control of the upper airway (e.g., neuromuscular disease, hypoglossal nerve palsy)
3. Member is unable to or does not have the necessary assistance to operate the HGNS sleep remote
4. Coexisting non-respiratory sleep disorders that would confound functional sleep assessment
5. Member is pregnant or plans to become pregnant
6. Member has severe cardiac disease (e.g., severe valvular heart disease, New York Heart Association class III or IV heart failure, myocardial infarction or severe cardiac arrhythmias within the past 6 months)
7. Severe restrictive or obstructive pulmonary disease
8. Persistent uncontrolled hypertension despite medication use
9. Moderate-to-severe pulmonary arterial hypertension

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 hypoglossal nerve stimulation (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

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Adherence and Result of Upper Airway Stimulation for OSA (ADHERE) registry data. Long-term follow-up suggests that therapy benefit is durable if patients adhere to therapy. 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; Woodson et al. 2018).

Randomized Controlled Trials

Strollo et al. (2014) completed the STAR trial, a multicenter prospective randomized controlled trial, which 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 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 a control group limited the validity of the results of this study. This study was 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 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.

Dedhia et al. (2024) conducted a double-blind, sham-controlled, randomized crossover clinical trial to evaluate the effects of HGNS on cardiovascular outcomes in patients with moderate-to-severe OSA. The study included 60 participants (n=60) from three academic medical centers who had already undergone HGNS implantation and were adherent to therapy. Individuals who had fallen asleep while driving within 1 year prior to HGNS implantation were excluded. Participants were predominately male (63%), had an average age of 67.3 years, a mean BMI of 28.7 kg/m^2, and a mean AHI at baseline of 33.1, indicating severe OSA. The study design involved two 4-week intervention periods in which each participant received active HGNS therapy during one period and sham therapy during the other, separated by a one-week washout period. The primary outcome was mean 24-hour systolic blood pressure (SBP), while secondary outcomes were pre-ejection period (PEP) to measure sympathetic nervous system activity, and flow-mediated dilation (FMD) to measure vascular health. Results showed no significant difference between active and sham therapy for 24-hour SBP (mean change of -0.18 mmHg, 95% CI: -2.21 to 1.84), PEP (mean change of 0.11 milliseconds, 95% CI: -5.43 to 5.66), or FMD (mean change of -0.17%, 95% CI: -1.88% to 1.54%). A per-protocol analysis of 20 patients who experienced at least 50% reduction in AHI between sham and active treatment, showed larger differences in cardiovascular outcomes, but none were statistically significant. No major adverse events related to HGNS were reported. The authors noted several methodological challenges, including difficulty in fully blinding participants (88% correctly guessed their treatment order) and potentially therapeutic effects of sham therapy due to minimal stimulation causing partial tongue motion. Other limitations included small sample size and inability to include severely excessively sleepy patients due to ethical concerns. The authors concluded that HGNS did not demonstrate differences in 24-hour blood pressure, sympathetic activity, or vascular function over the 10-week study period. The trial is registered with ClinicalTrials.gov (NCT03359096).

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

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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 determine 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.

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 among 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.

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

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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 studies included were prospective single-arm cohort studies.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Woodson et al. (2025) conducted a prospective, non-randomized clinical study examining a novel bilateral hypoglossal nerve stimulation system (HNSBL) in adults with moderate to severe obstructive sleep apnea who were unable to tolerate positive airway pressure therapy. The trial enrolled 115 adults aged 22-75 years with a BMI ≤32 kg/m², a baseline AHI of 15-65 events/hour, central/mixed apneas <25%, sufficient supine sleep, and no complete concentric palatal collapse on drug-induced sleep endoscopy. The study's co-primary effectiveness outcomes at 12 months were achievement of the Sher criteria (≥50% reduction in 4% AHI with final AHI < 20 events/hour) and at least a 25% reduction in oxygen desaturation index (ODI). By one year, 63.5% of participants met the AHI response definition ($p = .002$) and 71.3% met the ODI response threshold ($p < .001$). Among participants who completed 12-month polysomnography, significant improvements were observed in AHI, ODI, and sleep time with oxygen saturation <90% (all $p < .001$). Patient-reported outcomes also improved, including gains in functional sleep-related quality of life and reductions in daytime sleepiness and nocturnal obstruction symptoms. Snoring severity decreased markedly, and most participants expressed high satisfaction with therapy at 12 months. Safety monitoring identified serious adverse events in 8.7% of participants, most related to the procedure or the device. Additional non-serious events occurred but were largely self-limited and resolved within the first postoperative month. The authors noted that the absence of a comparator group, demographic homogeneity of the study population, participant attrition, and reliance on self-reported adherence were meaningful limitations. Despite these constraints, the trial demonstrated that bilateral hypoglossal nerve stimulation can produce clinically meaningful reductions in OSA severity and improvements in patient-centered outcomes in appropriately selected individuals.

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: AHI 0-15 (n=42), AHI 16-29 (n=765), AHI 30-50 (n=821), AHI 51-65 (n=258), and 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.

Heiser et al. (2019) and Suurna et al. (2021) reported on the ADHERE registry, which 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

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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.

National and Specialty Organizations

One hundred and thirty authors from OSA specialties including neurology, pulmonology, sleep medicine, otolaryngology, oral-maxillofacial surgery, dentistry, anesthesiology, psychiatry, cardiology, and sleep physiology came together to publish *International Consensus Statement on Obstructive Sleep Apnea* (Chang et al. 2023). 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.

The **American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)** recognizes HGNS as a safe and effective treatment option in select patient populations. In a 2023 consensus statement, AAO-HNS concluded HGNS is a safe and effective treatment for severe persistent OSA in children with Down syndrome (Ishman et al. 2023). Additionally, in a 2021 position statement, AAO-HNS supported HGNS as an effective second-line treatment for adults with moderate-to-severe OSA who are intolerant of or unable to achieve benefit with PAP therapy (AAO-HNS 2019).

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

The **Apnea Hypopnea Index (AHI)** measures the severity of OSA by quantifying the number of apneas (complete airway obstructions) and hypopneas (partial airway obstructions accompanied by oxygen desaturation or arousal) per hour of sleep. It's calculated by adding the total number of apneas and hypopneas, multiplied by 60, divided by total sleep time in minutes. AHI is measured in "events per hour" (Slowik et al. 2025).

Drug-induced sleep endoscopy (DISE) is a diagnostic procedure that evaluates the pattern and degree of airway collapse during sleep and is performed under sedation to simulate natural sleep conditions. The procedure assesses whether airway collapse is anterior-posterior (favorable for HGNS) or concentric (a contraindication for HGNS).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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

HCPCS (Healthcare Common Procedure Coding System)

Codes	Description
C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring insertion of a separate distal respiratory sensor electrode or electrode array
C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator
C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator
C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including

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	external power source and all system components
C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver

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

04/08/2026 Policy revised. Updated coverage criteria to reflect device specific criteria for Inspire and Genio System. IRO peer reviewed on March 3, 2026, by a practicing physician board certified in Otolaryngology.

04/09/2025 Policy reviewed. No changes to coverage criteria. IRO peer reviewed on March 7, 2025, by a practicing physician board certified in Otolaryngology.

06/12/2024 Policy revised. Updated criteria to 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 physician board-certified in Otolaryngology - Head and Neck Surgery.

06/14/2023 Policy revised. Updated coverage criteria to include indications for eligible pediatric patients with Down syndrome. IRO peer reviewed on May 9, 2023, by a practicing, board-certified physician in Otolaryngology – Head and Neck Surgery.

10/12/2022 Policy revised. Updated summary of medical evidence and references. IRO peer reviewed in September 2022 by a 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). IRO peer reviewed on September 24, 2021 by a practicing physician board certified in Sleep Medicine.

06/09/2021 Policy reviewed. No changes to coverage criteria.

06/17/2020 New policy. IRO Peer Review. April 2020. Practicing physician. Board-certified in Sleep Medicine.

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