MEDICAL POLICY

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Medical Policy Title	**Surgical Management of Sleep Disorders**
Policy Number	**7.01.41**
Current Effective Date	**January 22, 2026**
Next Review Date	**January 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Nasal Surgery

A. Nasal surgery is **medically appropriate** to correct a nasal obstruction that prohibits the use of continuous positive airway pressure (CPAP) device and bilevel positive airway pressure (BiPAP).

B. Septoplasty, turbinate reduction, and polypectomy are **not medically necessary** for obstructive sleep apnea (OSA).

II. Surgical Bypass of the Airway Tracheostomy

A. Tracheostomy is **medically appropriate** for the treatment of severe, life threatening OSA.

III. Upper Airway Surgery

A. Palatopharyngoplasty (e.g., Uvulopalatopharyngoplasty (UPPP), Uvulopharyngoplasty) **AND** Hyoid Suspensions for the treatment of OSA are **medically appropriate** when the following criteria are met:

1. Documented OSA with an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of 15 or greater events per hour, regardless of symptoms; **or**
2. Documented OSA with an AHI or RDI of five (5) to 14 events per hour, accompanied by symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, or documented cardiovascular diseases, including hypertension and ischemic heart disease; **and**
3. Failure of all forms of medical management of OSA, including documented intolerance to positive airway pressure (e.g., CPAP, BiPAP) or intolerance.

B. Tonsillectomy and Adenoidectomy:

1. Tonsillectomy and adenoidectomy are **medically appropriate** for the following indications:
   a. treatment of OSA; **or**
   b. to correct an upper airway obstruction that prohibits the use of CPAP/BiPAP.

C. Radiofrequency Ablation or Somnoplasty of Palatal Tissues is **not medically necessary** for the treatment of OSA.

D. Laser-assisted Uvulopalatoplasty (LAUP) is **not medically necessary** for the treatment of OSA.

E. Expansion Sphincter Pharyngoplasty/Expansion Sphincteroplasty (ESP) is **investigational.**

F. Injection Snoreplasty:

1. Injection Snoreplasty is **not medically necessary** for the treatment of snoring alone.
2. Injection Snoreplasty is **investigational** for the treatment of OSA.

G. Cautery-Assisted Palatal Stiffening Operation (CAPSO):

1. CAPSO is **not medically necessary** for snoring alone.
2. CAPSO is **investigational** for the treatment of OSA.

H. Palatal Implant System (e.g., Pillar Palatal Implant):

1. Palatal Implant Systems are **not medically necessary** for snoring alone.
2. Palatal Implant Systems are **investigational** for the treatment of OSA.

IV. Lower Airway Surgery

A. Jaw Realignment Surgery (e.g., inferior sagittal mandibular osteotomy, genioglossal advancement, hyoid myotomy and suspension, maxillomandibular osteotomy and advancement)*:*

1. Jaw realignment surgery is **medically appropriate** for the treatment of OSA in individuals who meet the criteria for UPPP, as stated in Policy Statement III.A.

B. Radiofrequency Ablation or Somnoplasty of the Base of the Tongue is **not medically necessary** for the treatment of OSA.

C. Tongue Suspension Suture Systems (e.g., AIRvance [formerly known as the Repose System], Encore System) are **investigational** for the treatment of OSA.

V. Hypoglossal Nerve/Upper Airway Stimulation

A. The approved United States Food and Drug Administration (FDA) hypoglossal nerve upper airway stimulation (e.g**.**, Inspire II Upper Airway Stimulation system, Inspire 3028 System for Upper Airway Stimulation (UAS) Therapy) device is **medically appropriate** for the treatment of moderate-to-severe OSA, when **ALL** the following criteria are met for each listed age group:

1. Adult ($\geq$18 years):

a. AHI $\geq$15 and $\leq$100;

b. $\leq$25% central apneas and mixed apneas (e.g., AHI and apneas confirmed with a in facility or attended polysomnography);

c. documentation of failure or inability to use or tolerate CPAP (e.g., residual AHI ≥15 or failure to use CPAP ≥4 hours per night for ≥5 nights per week);

d. documentation of all previous treatment measures and why they have been unsuccessful;

e. absence of complete concentric collapse of the soft palate; **and**

f. Body Mass Index (BMI) <40km/m2;

2. Adolescents or young adults (aged 13 to 18 years) with Down Syndrome:

a. AHI >10 and less than ≤50;

b. ≤25% central or mixed apneas;

c. are either contraindicated for adenotonsillectomy or do not respond effectively to the procedure;

d. do not have complete concentric collapse at the soft palate level on drug induced sleep endoscopy;

e. Body Mass Index ≤ 95th percentile for age;

f. have either a tracheotomy or have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance; **and**

g. have followed standard of care in considering all other alternative/adjunct therapies.

B. Upper airway stimulation therapy is **contraindicated** when the individual:

a. has any condition or procedure that would affect neurological control of the upper airway;

b. is unable or does not have the necessary assistance to operate the sleep remote;

c. is pregnant or plans to become pregnant;

d. has an implantable device that may have unintended interactions with the upper airway stimulation system (e.g., Inspire system).

C. Hypoglossal nerve/upper airway treatment of OSA that does not meet the above listed criteria in PS V.A. or B. is considered **investigational**.

VI. Surgical treatment for snoring without polysomnographic evidence of OSA is considered **not medically necessary**.

VII. Cardiac pacing or atrial overdrive pacing is **investigational** for the treatment of OSA.

VIII. Device Repair

A. Repair of a medically necessary device or components not under warranty will be considered **medically appropriate** when the following criteria are met:

1. Physician documentation includes **ALL** the following:

a. date of device implantation/initiation;

b. manufacturer warranty information, if applicable;

c. attestation that the individual has been compliant with the use of device and will continue to benefit from the use of device;

2. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

a. inadequate function interferes with activities of daily living; **and**

b. repair is expected to make the equipment fully functional (as defined by manufacturer).

B. Repair of equipment damaged due to the individual neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage.**

RELATED POLICIES

Corporate Medical Policy

1.01.06 Positive Airway Pressure Devices CPAP, BIPAP, APAP, and Noninvasive Positive Pressure Ventilators (NIV)

1.01.07 Medical Management Obstructive Sleep Apnea (OSA)

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.99 Sinus Excision/Destruction, Implants, and Repair

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Surgery is not the first treatment of choice for OSA. It is reserved for individuals who have failed all forms of medical management of OSA, or are intolerant of CPAP, BiPAP, ~~and~~ or oral appliances.

II. In severe OSA disease, surgery may not be curative, and follow-up studies may be warranted post-operatively.

III. For those individuals who have been found to have multiple levels or anatomical sites (e.g., hypopharyngeal, retropalatal, and/or retro lingual) of OSA on clinical evaluation, a simultaneous combination of surgical procedures may be appropriate for the best surgical outcome and to minimize operative risk. Nasal surgery is not considered part of a multi-level surgery to correct OSA. If a nasal obstruction precludes the use of CPAP, then nasal surgery to allow the use of CPAP should be performed first.

DESCRIPTION

Obstructive sleep apnea (OSA) is the cessation of airflow through the nose and mouth for at least 10

seconds with a respiratory effort noted and is usually associated with a reduction in blood oxygen saturation. Features of OSA include daytime somnolence, disordered sleep, and a variety of clinical symptoms. It is also common to find decreased motor and perceptual skills while awake, which correlates with the severity of hypoxia during sleep. The syndrome is most common in middle-aged, obese, male smokers.

In individuals with OSA, the normal pharyngeal narrowing is accentuated by anatomic factors, such as a short neck, elongated palate and uvula, or large tonsillar pillars with redundant lateral pharyngeal wall mucosa. OSA may also be associated with a wide variety of craniofacial abnormalities, including micrognathia, retrognathia or maxillary hypoplasia.

When anatomical obstructions exist, surgical interventions are used. Obstruction can occur at several different locations along the airway, and in specific circumstances, combined surgical procedures can offer a higher overall success rate than one single procedure alone. Due to the complexity of airway narrowing or collapse during sleep, one surgical procedure may not eradicate the person's sleep apnea. Procedures such as septoplasty, nasal turbinectomies or nasal polypectomies may be indicated for correction of nasal airway obstruction, their role in treating multi-level OSA is very limited.

When individuals with OSA are not able achieve benefit with non-invasive positive pressure therapy (PAP) or fail the gold standard of treatment in the form of CPAP, a second-line treatment may be a surgical option.

The goal of surgery is to enlarge the airway and prevent airway collapse and oxygen desaturation, to prevent the clinical symptoms of OSA: excessive daytime sleepiness, impaired cognition, and mood disorders. Surgery is site-specific, performed to enlarge a certain portion of the airway.

Types of Nasal Surgery

- Septoplasty corrects a deviated septum, which may obstruct the nasal airway.
- Turbinate reduction reduces the size of one of the three turbinate in each nostril, which can improve the size of the nasal airway. The surgery may be performed with lasers, cautery, or radiofrequency ablation.
- Polypectomy removes nasal polyps that obstruct the nasal airways.

Upper Airway Surgery

- Uvulopalatopharyngoplasty (UPPP) involves the removal of the uvula and trimming of the lower edge of the soft palate. The surgery may include several technical variations. All techniques include the basic UPPP procedure, but often additional surgery is performed, such as tonsillectomy. UPPP with inferior sagittal osteotomy with hyoid suspension is one variation proposed to improve the surgical outcome.
- Radio-frequency ablation of soft palate tissue, or somnoplasty system, uses a device consisting of an electrosurgical (RF) generator and tissue-coagulating electrodes that ablate soft tissues in the palate or uvula.
- Laser-assisted uvulopalatoplasty (LAUP) involves the progressive removal of the back edge of the

palate and reduction in the size of the uvula. It is most frequently performed with a carbon dioxide laser and is typically performed over several surgical sessions in an outpatient setting.

- Expansion sphincter pharyngoplasty/expansion sphincteroplasty (ESP) is a modification of a UPPP in which the lateral pharyngeal wall is stiffened to prevent collapse. ESP consists of a tonsillectomy, expansion pharyngoplasty, rotation of the palatopharyngeal muscle, partial uvulectomy, and closure of the anterior and posterior tonsillar pillars.
- Tonsillectomy and adenoidectomy are, respectively, procedures to remove enlarged tonsils, which may narrow the width of the upper airway, and the adenoids, which are at the back of the nose and may obstruct the nasal airway. Removal of tonsils and adenoids is performed most often in children with sleep apnea. Adenoids usually shrink with age and only rarely require removal in adults.
- Injection snoreplasty involves the injection of a sclerosing agent (tetradecyl sulfate/Sotradecol) into the soft palate, which causes scarring and subsequent stiffening of the soft palate. This is thought to reduce the flutter of the soft palate, which is the cause of primary snoring.
- Cautery-assisted palatal stiffening operation (CAPSO) is a procedure in which electrocautery is utilized to remove a portion of the soft palate and uvula. It is carried out under local anesthesia, on an outpatient basis.
- Palatal implant system involves insertion of three narrow bands of braided polyester under the skin of the soft palate using a delivery tool. The implant has been proposed for the treatment of snoring and for the treatment of palate-related mild to moderate sleep apnea. Once in place, the implant stiffens the palate by mechanical means and induces a fibrotic response that incapsulates and secures the implants, further stiffening the palatal tissue. Palatal implants, though designed to be permanent, are removable. Implantation is carried out under local anesthesia.

<u>Lower Airway Surgery</u>

- Jaw realignment surgery (e.g., inferior sagittal mandibular osteotomy, genioglossal advancement, hyoid myotomy and suspension, maxillomandibular osteotomy and advancement) is a more aggressive surgical procedure than UPPP. It has been used to relieve obstruction in OSA individuals who meet the criteria for UPPP.
- A tongue suspension suture system (e.g., Airvance, Medtronic, Inc) involves preventing the tongue from falling back during sleep. The Airvance System uses a titanium screw in the chin, which is attached to a permanent stitch through the tongue to pull it forward. The Encore System is similar to the Airvance System but creates a suture loop within the tongue without having to create penetrations through the mucosal surface of the tongue.
- Radiofrequency ablation, or Somnoplasty System, uses a device consisting of an electrosurgical (RF) generator and tissue-coagulating electrodes that ablate soft tissues, creating volumetric tissue reduction of the tongue.

<u>Surgical Bypass of the Airway</u>

- A tracheostomy bypasses the narrow segments of the airway that cause obstruction and creates an opening in the neck that allows the individual to breathe unobstructed at night. This is done in severe, life-threatening cases of sleep apnea.

Hypoglossal Nerve/Upper Airway Stimulation

- Electrical stimulation of the hypoglossal nerve has been proposed as a method of maintaining upper airway patency by augmenting tone to the upper airway. The implant device, which consists of a pulse generator, a stimulation lead, and a sensing lead, is designed to detect the ~~individual's~~ respiratory effort and maintain airway patency with mild stimulation of the hypoglossal nerve. Therapy settings are stored in the pulse generator and configured by the physician using an external programmer. The individual uses a remote to start therapy before going to sleep and to stop therapy when awakened. The sleep remote also provides the ability to pause therapy and to adjust stimulation amplitude within physician-defined limits.

Atrial Overdrive Pacing

- It has been found that bradycardia frequently occurs during episodes of apnea. Therefore, atrial overdrive pacing after implantation of a pacemaker has been proposed as a treatment to reduce the incidence of obstructive sleep apnea events.

SUPPORTIVE LITERATURE

Candidates for surgical options require appropriate selection. Factors to consider are the polysomnographic report, age, BMI, and objective upper airway evaluation measures.

Kent et al (2021) conducted a systematic review and meta-analysis to support the development of the American Academy of Sleep Medicine clinical practice guidelines on when to refer adults with OSA for surgical consultation. Findings show that surgical therapy (upper airway or bariatric surgery) is associated with clinically significant improvements in excessive daytime sleepiness, snoring, AHI, RDI, ODI, blood pressure and quality of sleep. The AASM guideline recommendations are based on a systematic review and meta-analysis of 274 studies of surgical interventions, including procedures such as Uvulopalatopharyngoplasty (UPPP), modified UPPP, MMA, tongue base suspension, and hypoglossal nerve stimulation (Kent et al 2021). The systematic review deemed most studies included data of low quality, consisting of mostly observational data.

LAUP studies have shown that a large proportion of patients post-operatively developed significant worsening of objective sleep parameters. Camacho et al (2017) conducted a systematic review and meta-analysis on the effectiveness and the outcomes of LAUP as a treatment for OSA. The review evaluated pre-and-post-operative outcomes such as AHI, oxygen saturation levels, and quality of life measurements. Twenty-three adult studies (717 patients) reported outcomes. LAUP reduced AHI by 32% among all participants. Individual participant data analyses demonstrated a 23% success rate (≥50% reduction in AHI and <20 events/hour) and an 8% cure rate. A total of 44% of patients had worsening of their AHI after LAUP. Lowest oxygen saturation (LSAT) improved minimally. Recommendations suggest that LAUP should be performed with caution or not perform at all given the unfavorable results of study.

Snoreplasty and CAPSO are intended treatment therapies for snoring, and not for the treatment of

OSA (Lee et al 2014). Most published studies on this treatment have been non-randomized, observational studies with highly selected enrolled participants. These studies also fail to report long-term outcomes or recurrence rates.

The Pillar Palatal Implant received FDA approval for the treatment of snoring in 2003 and as a treatment for OSA in September 2004. There is insufficient peer-reviewed evidence to support the use of the Pillar implant as a treatment for OSA. The literature consists of small case series investigating its use for snoring. Studies with OSA patients had very small sample sizes and limited follow-up, and were vendor sponsored (Nordgard et al (2006); Friedman et al (2006)).

Many individuals with OSA also suffer from nocturnal bradycardia or tachyarrhythmias. It has been observed that, in some patients, the use of a pacemaker to increase the heart rate and cardiac function during sleep could also reduce the incidence of apneic episodes. Although a clinical study by Garrigue et al (2002) found that atrial overdrive pacing significantly reduced the number of episodes of central and obstructive sleep apnea, but these positive findings have not been validated in any of the newer, well-designed studies. Atrial overdrive pacing has not been found to reduce the number of apnea and/or hypopnea events in patients with OSA (Krahn et al (2006); Unterberg et al (2005); Luthje et al (2005); Simantirakis et al (2005); Pepin et al (2005)).

Upper airway stimulation (UAS) leads to significant reductions in the AHI, the ODI, and the ESS in older patients, despite higher age with multiple co-morbidities. Advanced age was not a limiting factor for surgical procedure or treatment outcomes. The main result of this study is a significant reduction of the AHI in younger and older subjects: 84% decrease in younger subjects and 80.8% decrease in older subjects where the AHI declined below a level of 15 events per hour (the generally accepted values that define mild sleep apnea). Furthermore, the level of daytime sleepiness also declined in 69.6% of younger and in 72% of older subjects where the value of ESS was below 10 points. (Zhu et al 2018).

The largest cohort study done to date, which focused exclusively on UAS therapy outcomes, consisted of a study of 47 patients, 30 of whom had undergone a previous surgery and 16 of whom had not suffered from moderate-to-severe OSA, but were surgical candidates for Hypoglossal Nerve Stimulation (HNS_ therapy. The study examined AHI and nadir oxyhemoglobin saturation (NOS) as measured by polysomnography; secondary measures included ESS. The study revealed an overall reduction in AHI by 90%, which translated to a success rate of 96% and cure rate of 81%. (Mahmoud et al 2018).

Patients with moderate-to-severe OSA and an inability to adhere to positive pressure therapy, who underwent HGNS, were compared to a historical cohort of patients who were intolerant of CPAP who underwent UPPP. Data included BMI, as well as pre- and post-implant AHI. UAS resulted in an approximately 90% reduction in AHI, while traditional airway surgery resulted in an approximately 30% reduction in AHI. In addition, 65% of the patients in the UAS cohort demonstrated a reduction in AHI from the moderate-to-severe range into the normal range (AHI <5), compared to only 20% of the patients in the UPPP group. (Shah et al 2018).

Liu et al (2022) published a systematic review investigating HNS in adolescents with Down Syndrome and OSA. A total of nine studies were included with a follow up period ranging from two to 58

months; six studies had sample sizes fewer than ten patients. The largest of the included studies was a prospective cohort study published by Yu et al (2022), which is summarized below. In an analysis that included 104 patients, AHI scores were significantly reduced in patients after HNS (mean AHI reduction, 17.43 events/h; 95% CI, 13.98 to 20.88events/h; p<.001). Similarly, in an analysis that included 88 patients, OSA-18 survey scores were significantly reduced after HNS (mean OSA-18 reduction, 1.67; 95% CI, 1.27 to 2.08; p<.001).

Yu et al (2022) reported on the safety and effectiveness of HNS in 42 adolescents with Down Syndrome and severe OSA (AHI of 10 events/h or greater). This was a single-group, multicenter, cohort study with a 1-year follow-up that included non-obese (BMI <95%) children and adolescents aged 10 to 21 years who were refractory to adenotonsillectomy and unable to tolerate CPAP. Patients who were included had an AHI between 10 and 50 on baseline polysomnography (PSG); the mean baseline AHI was 23.5 (SD, 9.7). All patients included tolerated HNS without any intraoperative complications. The most common complication was tongue or oral discomfort or pain, which occurred in 5 (11.9%) patients and was temporary, lasting weeks or rarely, months. Four patients (9.5%) had device extrusion resulting in readmissions to replace the extruded device. At 12 months, there was a mean decrease in AHI of 12.9 (SD, 13.2) events per hour (95% CI, -17.0 to -8.7 events/h). At the 12-month PSG, 30 of 41 patients (73.2%) had an AHI of less than 10 events/h, 14/41 patients (34.1%) had an AHI of less than 5 events/h, and 3/41 patients (7.3%) had an AHI of less than 2 events/h. There was also a significant improvement in quality-of-life outcomes. The mean improvement in the OSA-18 total score was 34.8 (SD, 20.3;95% CI, -42.1 to -27.5) and the ESS improved by 5.1 (SD, 6.9; 95% CI, -7.4 to -2.8).

Alrubasy et al (2024) evaluated the efficacy of Apnex, Inspire, and ImThera HNS devices in changing the severity of OSA in adults (>18). The efficacy of each device was assessed individually, and the reported outcomes were analyzed at short-term (≤1 year) and long term (>1 year) intervals. Data was based on a total of 549 middle aged (55 ± 9.2) overweight (BMI=29 ± 3.9) individuals. The Inspire device significantly reduced the AHI by -20.14 events/hour (h) in the short term and -15.91 events/h in the long term. ODI decreased by -14.16 events/h (short term) and -12.95 events/h (long term). Patient-reported outcomes showed decreased ESS scores by -5.02 (short term) and -4.90 (long term) and FOSQ scores by 3.58 (short term) and 3.28 (long term). The Apnex device and the ImThera devices featured similar improvements but to a lesser extent. No significant differences in efficacy were observed among the three devices. Study findings were consistent with previous meta-analyses examining the effects of HNS on OSA.

Kim et al (2023) compared HNS to other OSA treatments in a systematic review and meta-analysis. Studies included measured polysomnography parameters and assessed sleep apnea-related quality of life (Epworth Sleepiness Scale (ESS)) both before and after HNS, and compared these outcomes with control, CPAP, or airway surgery (uvulopalatopharyngoplasty, expansion sphincter pharyngoplasty, or tongue base surgery) groups. A total of 10 studies with 2209 patients (mean BMI ≤30 kg/m2 in every study) who were treated with HNS or alternative interventions. HNS improved post-treatment AHI <10 and <15 events/hour compared with other surgical options including uvulopalatopharyngoplasty, expansion sphincterpharyngoplasty, or tongue-based surgery (odds ratio [OR]; 5.33;95% CI, 1.21 to 23.42).

ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3) investigated the efficacy and safety of targeted HNS of the proximal hypoglossal nerve in individuals with moderate-to-severe OSA (AHI 20-60 events per hour) and a BMI of 35 kg/m2 or less (Schwartz et al. 2023). This was a multicenter, randomized trial where all individuals (N=138) were implanted with the HNS system (aura6000; ImThera Medical) and randomly assigned 2:1 to HNS device activation at one or four months after implant for the treatment and control groups, respectively. Efficacy was measured at month four, and after 11 months of therapy (study months 12 and 15 for treatment and control groups, respectively). The study included mostly males (86.2%) and Caucasian individuals (91.3%). The results demonstrated that at month four, the treatment group had significantly better outcomes compared to the control group for AHI and oxygen desaturation index (ODI) scores. After 11 months of active therapy, the difference between the treatment and control groups was not statistically significant for AHI (RR, -7.5; 95% CI, -16 to 1.4) but remained significant for ODI (RR, 10.4; 95% CI, 1.6 to 18.8). The authors noted that the results should only be applied to individuals with moderate to severe OSA and a BMI of 35 kg/m2 or less.

Woodson et al (2024) published the DREAM study, which aimed to evaluate the safety and efficacy of a novel bilateral hypoglossal nerve stimulation device (HNSBL), the Genio device. Adult patients with moderate-to-severe obstructive sleep apnea who refused, failed, or did not tolerate positive airway pressure therapy underwent implantation and nightly use of the Genio system. The Genio system was implanted in 113 participants. Eleven serious adverse events occurred in ten (8.7%) participants. AHI and oxygen desaturation index responses were achieved in 63.5% (73/115, P = .002) and 71.3% (82/115, P < .001), respectively. Secondary endpoint analysis revealed significant changes in mean AHI (218.3 ± 11.8 events/h, P < .001), oxygen desaturation index (217.7 ± 14.6 events/h, P < .001), and sleep time with blood oxygen saturation less than 90% (6.9 ± 10.7%, P < .001). The study design had several limitations including a small sample size, homogeneous study sample, industry sponsorship and lack of follow up or study completion by 27 participants.

PROFESSIONAL GUIDELINE(S)

National Institute for Health and Care Excellence 2017 recommendation states that HNS for moderate to severe obstructive sleep apnea should only be used with special arrangements for clinical governance, in clinical trials, stating the evidence on the safety and efficacy of the HNS is limited in quantity and quality.

The AASM (2021) strongly recommends that clinicians discuss a referral to a sleep surgeon with adults with OSA and body mass index (BMI) <40 kg/m2 who are intolerant or unaccepting of PAP. The AASM makes a conditional recommendation that clinicians discuss referral to a sleep surgeon with adults with OSA, BMI <40 kg/m2, and persistent inadequate PAP adherence due to pressure-related side effects. The available data (very low-quality), suggests that upper airway surgery has a moderate effect in reducing minimum therapeutic PAP level and increasing PAP adherence. In adults with OSA and obesity (class II/III, BMI >35) who are intolerant or unaccepting of PAP, the AASM strongly recommends discussion of referral to a bariatric surgeon, along with other weight-loss strategies.

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS; 2021) position

statement supports surgical management of OSA when part of a comprehensive approach in the medical and surgical management of adults with OSA. Approved treatments include:

- Tracheostomy
- Nasal and pharyngeal airway surgery
- Tonsillectomy and adenoidectomy
- Palatal advancement
- UPPP
- Genioglossal advancement
- Hyoid myotomy
- Midline glossectomy
- Tongue suspension
- Maxillary and mandibular advancement
- Hypoglossal nerve stimulation as an effective second-line treatment of moderate-to-severe OSA.

According to the 2021 American Academy of Sleep Medicine (AASM) clinical practice guidelines, PAP therapy is strongly recommended as the first-line treatment for adults with OSA, especially those experiencing excessive daytime sleepiness. The guidelines support initiating PAP therapy using either auto-adjusting PAP (APAP) at home or in laboratory titration and recommend ongoing treatment with CPAP or APAP. The guidelines highlight that the clinical effectiveness of PAP therapy may be limited for individuals who struggle with adherence or do not experience sufficient therapeutic benefit. In such situations, alternative treatment options including surgical interventions may be more suitable, depending on the individual's specific circumstances and needs.

The AASM holds the position that while home sleep apnea testing (HSAT) is appropriate for diagnosing OSA in select adult populations, in laboratory PSG remains the preferred standard for more complex clinical scenarios, particularly when:

- Precise measurement of the Apnea-Hypopnea Index (AHI) is required;
- Exclusion of central sleep apnea is clinically important; or
- When advanced therapies such as HNS (e.g., Inspire therapy) are being considered.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates sleep devices and appliances as medical devices. All sleep devices and appliances including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Dec 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Dec 11]

On April 30, 2014, the FDA granted pre-market approval for the Inspire Upper Airway Stimulation (UAS) system (Inspire Medical Systems) for use in treating a subset of individuals, aged 22 years and older, with moderate-to-severe obstructive sleep apnea (AHI of 20 to 65) who have failed or could not tolerate CPAP treatments, who do not have complete concentric collapse at the level of the soft palate and a body mass index (BMI) less than 32.

In June 2023, the FDA expanded indications for Inspire UAS system. The update increased the upper limit of the AHI to 100 events per hour from 65 and raised the BMI warning from 32 to 40. The FDA lowered the age to 18 years old for individuals with moderate to severe OSA. The FDA added indications for pediatric individuals aged 13-18 years old with Down Syndrome and who have an AHI greater than 10 and less than 50. Inspire Medical Systems, Inc. [Internet] [accessed 2025 Dec 11] Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008S090A.pdf

On August 8, 2025, the FDA granted premarket approval for the Genio system for a subset of patients who meet specific criteria.

The FDA defines positive airway pressure (PAP) failure as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

1. Inability to use PAP (greater than five (5) nights per week of usage; usage defined as greater than four (4) hours of use per night); or
2. Unwillingness to use PAP (for example, an individual returns the PAP system after attempting to use it).

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
21141-21155, 21193-21206, 21244	Jaw realignment surgery (code ranges)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft

Code	Description
30620	Septal or other intranasal dermatoplasty (does not include obtaining graft)
31600	Tracheostomy, planned (separate procedure)
41512 (E/I)	Tongue base suspension, permanent suture technique
41530 (NMN)	Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session
42145	Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)
42820	Tonsillectomy and adenoidectomy; younger than age 12
42821	Tonsillectomy and adenoidectomy; age 12 or over
64568	Open implantation cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
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
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off

Code	Description
	cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

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HCPCS Codes

Code	Description
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring insertion of a separate distal respiratory sensor electrode or electrode array (effective 01/01/2026)
C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components (effective 01/01/2026)
C9727 (E/I)	Insertion of implants into the soft palate; minimum of three implants
S2080 (NMN)	Laser-assisted uvulopalatoplasty (LAUP)

ICD10 Codes

Code	Description
F51.8	Other sleep disorders not due to a substance or known physiological condition
G47.00	Insomnia, unspecified
G47.10	Hypersomnia, unspecified
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.30-G47.39	Sleep apnea (code range)
G47.69	Other sleep related movement disorders
G47.8-G47.9	Other and unspecified sleep disorders (code range)

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SEARCH TERMS

Airvance, Atrial overdrive pacing, Aura6000 System, CAPSO, Encore, HGNS, Hypoglossal Nerve Stimulation, Inspire II Upper Airway Stimulation System, LAUP, Pillar, Repose, Snoreplasty, Somnoplasty, UPPP

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Surgical management of obstructive sleep apnea is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

11/19/99, 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18, 03/21/19, 03/19/20, 03/18/21, 03/24/22, 03/23/23, 03/21/24, 04/17/25, 08/21/25, 01/22/26

Date	Summary of Changes
10/22/26	• Code edit, added C8007 and C8011. Policy intent unchanged.

01/22/26	• Annual Review; revised the hypoglossal nerve upper airway stimulation policy statement to make it applicable to any device and added new investigational statement for Hypoglossal nerve/upper airway treatment of OSA.
08/21/25	• Off-cycle comprehensive review. Updated the hypoglossal nerve stimulation criteria to align with U.S. FDA guidance, including revised age parameters for adolescents and young adults with Down syndrome.
01/01/25	• Summary of changes tracking implemented.
11/19/99	• Original effective date