LifeWise
Health Plan of Washington

MEDICAL POLICY – 7.01.554
Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

BCBSA Ref. Policy: 7.01.101

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Introduction

Obstructive sleep apnea (OSA) is a blockage in the upper part of the airway. The blockage is usually from throat muscles folding down, the tongue falling into the airway, or large tonsils or adenoids getting in the way. Positive airway pressure (PAP) devices are very effective in treating sleep apnea. A PAP device works by increasing air pressure in the throat to prevent it from collapsing as a person breathes. When a PAP device doesn't work or there are other medical reasons, surgery can be a way to treat sleep apnea. There are a number of different types of surgery, but they generally treat OSA by removing extra tissue in the throat to widen the airway. Another treatment is using a stimulator on the hypoglossal nerve to treat OSA. There are a number of other surgeries or devices that are still being studied. They are not covered because there is not enough medical evidence to show they work. This policy discusses when medically necessary surgeries for OSA may be approved.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

We will review for medical necessity these elective surgical procedures.

The surgical procedure subject to medical necessity review for site of service addressed in this policy is limited to:

- **Uvulopalatopharyngoplasty (UPPP)**

Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

Site of Service for Elective Surgical Procedures	Medical Necessity
Medically necessary sites of service: • **Off campus-outpatient hospital/medical center** • **On campus-outpatient hospital/medical center** • **Ambulatory Surgical Center**	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.**

Inpatient hospital/medical center	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the individual has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):**
	• Anesthesia Risk
	  ○ ASA classification III or higher (see **definition**)
	  ○ Personal history of complication of anesthesia
	  ○ Documentation of alcohol dependence or history of cocaine use
	  ○ Prolonged surgery (greater than 3 hours)
	• Cardiovascular Risk

Site of Service for Elective Surgical Procedures	Medical Necessity
	○ Uncompensated chronic heart failure (**NYHA class** III or IV) ○ Recent history of myocardial infarction (MI) (less than 3 months) ○ Poorly controlled, resistant hypertension* ○ Recent history of cerebrovascular accident (less than 3 months) ○ Increased risk for cardiac ischemia (drug eluting stent placed for less than 1 year or angioplasty less than 90 days) ○ Symptomatic cardiac arrhythmia despite medication ○ Significant valvular heart disease • Liver Risk ○ Advance liver disease (MELD Score greater than 8)** • Pulmonary Risk ○ Chronic obstructive pulmonary disease (COPD) (FEV1 less than 50%) ○ Poorly controlled asthma (FEV1 less than 80% despite treatment) ○ Moderate to severe obstructive sleep apnea (OSA)*** • Renal Risk ○ End stage renal disease (on dialysis) • Other ○ Morbid obesity (BMI greater than or equal to 50) ○ Pregnancy ○ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria]) ○ Anticipated need for transfusion(s) **Note:** * 3 or more drugs to control blood pressure ** **https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease** *** Moderate-AHI greater than or equal to 15 and less than or equal to

Site of Service for Elective Surgical Procedures	Medical Necessity
	30, Severe-AHI greater than or equal to 30 ****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)
Inpatient hospital/medical center	**This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.**

Treatment	Medical Necessity
Contract limitations	**Some health plan contracts do not have benefits to cover orthognathic surgery. Refer to member contract language for benefit determination where applicable.**
Palatopharyngoplasty	**Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) may be considered medically necessary for the treatment of clinically significant obstructive sleep apnea syndrome (OSA) in appropriately selected adult individuals who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance.** **Note**: Clinically significant OSA is defined in the **Related Information** section.
Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery	**Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered medically necessary in appropriately selected adult individuals with clinically significant OSA and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of CPAP or failed an adequate trial of an oral appliance.** **Note:** Clinically significant OSA is defined in the **Related Information** section.

Treatment	Medical Necessity
Adenotonsillectomy	**Adenotonsillectomy may be considered medically necessary in pediatric individuals with clinically significant OSA and hypertrophic tonsils.** **Note**: Clinically significant OSA is defined in the **Related Information** section.
Hypoglossal nerve stimulation	**Hypoglossal nerve stimulation may be considered medically necessary in adults with OSA under the following conditions:** • Individuals aged 18 years and older; **and** • AHI greater than or equal to 15 and less than or equal to 100 with less than or equal to 25% central apneas; **and** • CPAP failure (residual AHI greater than or equal to 15 or inability to tolerate CPAP greater than or equal to 4hrs per night for greater than or equal to 5 nights per week) or inability to tolerate CPAP; **and** • Body mass index (BMI) less than or equal to 35 kg/m^2; **and** • Absence of complete concentric collapse at the soft palate level as seen on drug induced sleep endoscopy (see **Related Information**) **Hypoglossal nerve stimulation may be considered medically necessary in individuals with Down syndrome and OSA under the following conditions:** • Aged 13 to 18 years; **and** • AHI greater than 10 and less than 50 with less than or equal to 25% central apneas after prior adenotonsillectomy; **and** • Have either a tracheotomy or be ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliant use, or refusal to use the device; **and** • Body mass index (BMI) less than or equal to 95th percentile for age; **and** • Absence of complete concentric collapse at the soft palate level as seen on drug induced sleep endoscopy (See **Related Information**)

Treatment	Medical Necessity
	Implantable hypoglossal nerve stimulators are investigational for all indications, other than what is listed above. **Surgical treatment of OSA that does not meet any of the above criteria may be considered not medically necessary.**
All interventions in the absence of documented OSA	**All interventions for the treatment of snoring in the absence of documented OSA (snoring alone is not considered a medical condition) are considered not medically necessary, including:** • LAUP (laser-assisted uvulopalatoplasty) • Palatal stiffening procedures • Radiofrequency volumetric tissue reduction of the palate

Treatment	Investigational

Minimally invasive surgical procedures	**The following minimally invasive surgical procedures are investigational for the sole or adjunctive treatment of OSA or upper airway resistance syndrome (UARS):**
	• Endoscopically assisted nasomaxillary expansion
	• Laser-assisted uvulopalatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues
	• Palatal stiffening procedures including, but not limited to:
	  ○ Cautery-assisted palatal stiffening operation (CAPSO)
	  ○ Implantation of palatal implants (e.g., Pillar Palatal Implant)
	  ○ Injection of a sclerosing agent
	• Radiofrequency volumetric tissue reduction of the tongue (e.g., Somnoplasty), with or without radiofrequency reduction of the palatal tissues
	• Tongue base suspension (e.g., Airvance System, formerly the Repose Tongue and Hyoid Suspension System, Encore system)
	• All other minimally invasive surgical procedures not described above

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Uvulopalatopharyngoplasty (UPPP):
  - Documented clinically significant obstructive sleep apnea (OSA) with apnea hypopnea index (AHI)
  - Documentation that the individual has failed or does not tolerate nasal continuous positive airway pressure (CPAP)
- Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery:
  - Documented clinically significant OSA with AHI
  - Objective documentation of hypopharyngeal obstruction and that the individual has failed or does not tolerate nasal CPAP
- Adenotonsillectomy:
  - Documented OSA with AHI
  - Physical exam shows enlarged tonsils
- Hypoglossal nerve stimulation:
  - Age of individual, AHI, central apneas, CPAP failure, BMI, and absence of complete concentric collapse at the soft palate level
    - If individual has Down syndrome, all of the above + documentation of adenotonsillectomy

Coding

Code	Description
CPT	
21199	Osteotomy, mandible, segmental; with genioglossus advancement
21685	Hyoid myotomy and suspension
41512	Tongue base suspension, permanent suture technique
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
42145	Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)
42299	Unlisted procedure, palate, uvula

Code	Description
42950	Pharyngoplasty (plastic or reconstructive operation on pharynx)
64568	Open implantation of 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
HCPCS	
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C9727	Insertion of implants into the soft palate; minimum of three implants
S2080	Laser-assisted uvulopalatoplasty (LAUP)

Related Information

Clinically significant obstructive sleep apnea (OSA) is defined as those individuals who have:

- Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of 15 or more events per hour, or
- AHI or RDI of at least 5 events per hour with one or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

Clinically significant OSA is defined as those pediatric individuals who have:

- AHI or RDI of at least 5 per hour, or
- AHI or RDI of at least 1.5 per hour in an individual with excessive daytime sleepiness, behavioral problems, or hyperactivity.

Continuous positive airway pressure is the preferred first-line treatment for OSA for most individuals. A smaller number of individuals may use oral appliances as a first-line treatment. The AHI is the total number of events (apnea or hypopnea) per hour of recorded sleep. The RDI is the total number of events (apnea or hypopnea) per hour of recording time. An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow compared with baseline, and with at least a 4% oxygen desaturation.

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. Hypoglossal nerve stimulation 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 HNS and is an exclusion criterion for hypoglossal nerve stimulation from the US Food and Drug Administration (FDA).

Definition of Terms

American Society of Anesthesiologists (ASA) Score:

ASA 1 A normal healthy patient.
ASA 2 A patient with mild systemic disease.
ASA 3 A patient with severe systemic disease.
ASA 4 A patient with severe systemic disease that is a constant threat to life.
ASA 5 A moribund patient who is not expected to survive

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Table 1. Terminology and Definitions for Obstructive Sleep Apnea

Terms	Definitions and Criteria
Respiratory event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by greater than or equal to 90% of the pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as greater than or equal to 2 missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of the pre-event baseline for at least 10 seconds in association with either at least 3% or 4% decrease in arterial oxygen desaturation (depending on the scoring criteria) or an arousal. Hypopneas in children are scored by a greater than or equal to 50% drop in nasal pressure and either a greater than or equal to 3% decrease in oxygen saturation or an associated arousal.
RERA	Respiratory event-related arousal (RERA) is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increasing respiratory effort, terminating in an arousal but not otherwise meeting criteria for apnea or hypopnea
Respiratory event reporting	
AHI	The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in home sleep studies when actual sleep time from EEG is not available.
Diagnosis	

Terms	Definitions and Criteria
OSA	Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
Mild OSA	In adults: AHI of 5 to 15 In children: AHI greater than or equal to 1 to 5
Moderate OSA	Adults: AHI of 15 to 30 Children: AHI of 5 to 10
Severe OSA	Adults: AHI greater than or equal to 30 Children: AHI greater than 10
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.
Treatment	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP
PAP	Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP).
PAP failure	Usually defined as an AHI greater than 20 events per hour while using PAP
PAP intolerance	CPAP use for less than 4 hours per night for greater than or equal to 5 nights per week, or refusal to use PAP. PAP intolerance may be observed in patients with mild, moderate, or severe OSA

AHI: Apnea/Hypopnea Index; APAP: auto-adjusting positive airway pressure; Bi-PAP: Bi-level positive airway pressure; CPAP: continuous positive airway pressure; EEG: electroencephalogram; OSA: obstructive sleep apnea; PAP: positive airway pressure; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal

Evidence Review

Description

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. For individuals who have failed conservative therapy, established surgical approaches may be indicated. This policy addresses minimally invasive surgical procedures for the treatment of OSA. They include laser-assisted

uvuloplasty, tongue base suspension, radiofrequency volumetric reduction of palatal tissues and base of tongue, palatal stiffening procedures, and hypoglossal nerve stimulation (HNS). This policy does not address conventional surgical procedures such as uvulopalatopharyngoplasty (UPPP), hyoid suspension, surgical modification of the tongue, maxillofacial surgery, or adenotonsillectomy.

Background

Obstructive Sleep Apnea

OSA is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. The hallmark symptom of OSA is excessive daytime sleepiness, and the typical clinical sign of OSA is snoring, which can abruptly cease and be followed by gasping associated with a brief arousal from sleep. The snoring resumes when the individual falls back to sleep, and the cycle of snoring/apnea/arousal may be repeated as frequently as every minute throughout the night. Sleep fragmentation associated with the repeated arousal during sleep can impair daytime activity. For example, adults with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles (i.e., cars, trucks, or heavy equipment). OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in individuals with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

There are racial and ethnic health disparities seen for OSA, impacting the prevalence of disease and accessibility to treatment options, particularly affecting children. Black children are 4 to 6 times more likely to have OSA than White children.[1] Among young adults 26 years of age or younger, African American individuals are 88% more likely to have OSA compared to White individuals. Another study found that African American individuals 65 years of age and older were 2.1 times more likely to have severe OSA than White individuals of the same age group. These health disparities may affect accessibility to treatment for OSA and impact health outcomes. One analysis of insurance claims data, including over 500,000 individuals with a diagnosis of OSA, found that increased age above the 18- to 29- year range ($p<.001$) and Black race ($p=.020$) were independently associated with a decreased likelihood of receiving surgery for

sleep apnea.[2] Lee et al (2022) found that Black men had a continuous mortality increase specifically related to OSA over the study period (1999 to 2019; annual percentage change 2.7%; 95% confidence interval, 1.2 to 4.2) compared to any other racial group.[3]

Summary of Evidence

For individuals who have OSA who receive laser-assisted uvulopalatoplasty (LAUP), the evidence includes a single randomized controlled trial (RCT). The relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The trial indicates reductions in snoring, but limited efficacy on the Apnea/Hypopnea index (AHI) or symptoms in individuals with mild-to-moderate OSA. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive radiofrequency (RF) volumetric reduction of palatal tissues and base of tongue, the evidence includes two sham-controlled randomized trials and a prospective, single-arm cohort study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Single-stage RF to palatal tissues did not improve outcomes compared with sham. Multiple sessions of RF to the palate and base of tongue did not significantly (statistically or clinically) improve Apnea/Hypopnea Index (AHI), and the improvement in functional outcomes was not clinically significant. The prospective cohort study included 56 individuals with mild-to-moderate OSA who received 3 sessions of office-based multilevel radiofrequency ablation. Results demonstrated improvement in AHI and Oxygen Desaturation Index (ODI) at the 6-month follow up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive palatal stiffening procedures, the evidence includes two sham-controlled randomized trials and several case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The two RCTs differed in their inclusion criteria, with the study that excluded individuals with Friedman tongue position of IV and palate of 3.5 cm or longer reporting greater improvement in AHI (45% success) and snoring (change of -4.7 on a 10-point visual analog scale) than the second trial. Additional studies are needed to corroborate the results of the more successful trial and, if successful, define the appropriate selection criteria. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive tongue base suspension, the evidence includes a feasibility RCT with 17 individuals. Relevant outcomes are symptoms, functional outcomes,

quality of life, and treatment-related morbidity. The single RCT compared tongue suspension plus UPPP with tongue advancement plus UPPP and showed success rates of 50% to 57% for both procedures. Additional RCTs with a larger number of subjects are needed to determine whether tongue suspension alone or added to UPPP improves the net health outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive HNS, the evidence includes systematic reviews, three RCTs, nonrandomized prospective studies, nonrandomized studies with historical controls, and prospective single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A double-blind, multicenter RCT of 89 adults with moderate-to-severe OSA who did not tolerate CPAP found significant short-term improvement in AHI, Epworth Sleepiness Score, and quality of life measures with HNS compared to sham stimulation. The study was limited by a short duration of follow-up and lack of diversity among included participants. Another RCT including 138 individuals with moderate-to-severe OSA who did not tolerate CPAP compared outcomes for individuals who received HNS therapy at 1 or 4 months after implant for the treatment and control groups, respectively. Results demonstrated significant short-term improvement in AHI and ODI when comparing HNS to no HNS at month 4. However, after 11 months of active therapy, the difference between the treatment and control groups was not statistically significant for AHI but remained significant for ODI in favor of the treatment group. This trial was also limited by a lack of diverse individuals, as well as a lack of a true control group for long-term outcomes. HNS has shown success rates for about two thirds of a subset of individuals who met selection criteria that included AHI, Body mass index (BMI) (less than or equal to 32 or less than or equal to 35 kg/m^2), and favorable pattern of palatal collapse across nonrandomized trials. These results were maintained out to five years in the pivotal single-arm study. The single prospective comparative study of individuals who received HNS versus individuals who were denied insurance coverage for the procedure has a high potential for performance bias. For children and adolescents with OSA and Down Syndrome who are unable to tolerate CPAP, the evidence includes a systematic review and a prospective study of 42 individuals. The systematic review investigated HNS in adolescents with Down Syndrome and OSA and demonstrated significant improvement in AHI and OSA-18 survey scores after HNS. A study of 42 individuals with Down Syndrome and OSA found a success rate of 73.2% with 4 device extrusions corrected with replacement surgery. Limitations of the current evidence base preclude determination of who is most likely to benefit from this invasive procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. (See **Clinical Input** below)

For individuals with OSA who receive endoscopically assisted maxillary expansion, the evidence includes a retrospective study with no control group and a sample size of 100 and no comparator. Cone beam computed tomography was conducted preoperatively and four weeks post completion of the maxillary expansion process. The results showed that 96% had successful expansion defined as separation of the midpalatal suture at least 1mm from anterior nasal spine to posterior nasal spine and showed improved air flow dynamics demonstrated by computational fluid dynamics[54]. However, there was no pre and post measurement of OSA findings or correlations with this study and no long-term durability measurements beyond that of four weeks. There is insufficient evidence in the peer-reviewed published scientific literature to support the safety and efficacy of endoscopically assisted maxillary expansion as a treatment for obstructive sleep apnea.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 2**.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05592002	A Multicenter Study to Assess the Safety and Effectiveness of the Genio Dual-sided Hypoglossal Nerve Stimulation System for the Treatment of Obstructive Sleep Apnea in Subjects With Complete Concentric Collapse of the Soft Palate	124	Oct 2027
NCT02413970[a]	Inspire Upper Airway Stimulation System (UAS): Post-Approval Study Protocol Number 2014-001	127	Jun 2025
NCT03868618[a]	A Multicenter Study to Assess the Safety and Effectiveness of the Genio Dual-sided Hypoglossal Nerve Stimulation System for the Treatment of Obstructive Sleep Apnea in Adults Subjects	115	Feb 2028
NCT03763682[a]	A Multicentre, Prospective, Open-label, 2 Groups Study to Assess the Safety and Performance of the Genio Bilateral	42	Dec 2023(status unknown)

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Hypoglossal Nerve Stimulation System for the Treatment of Obstructive Sleep Apnoea in Adult Patients With and Without Complete Concentric Collapse of the Soft Palate		
NCT04801771[a]	Effects of Hypoglossal Nerve Stimulation on Cognition and Language in Down Syndrome and Obstructive Sleep Apnea	57	Mar 2025
NCT04031040[a]	A Post-market Clinical Follow up of the Genio System for the Treatment of Obstructive Sleep Apnea in Adults (EliSA)	110	Oct 2025
NCT02907398[a]	Adherence and Outcome of Upper Airway Stimulation (UAS) for OSA International Registry	5000	Dec 2025
NCT04950894[a]	Treating Obstructive Sleep Apnea Using Targeted Hypoglossal Neurostimulation	150	Jul 2024

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2018 Input

Clinical input was sought to help determine whether the use of HNS for individuals with OSA would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from two respondents, including one specialty society-level response and physicians with academic medical center affiliation.

For individuals who have OSA who receive HNS, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in subgroups of appropriately selected patients. One

subgroup includes adult patients with a favorable pattern of non-concentric palatal collapse. The alternative treatment for this anatomical endotype is maxillo-mandibular advancement (MMA), which is associated with greater morbidity and lower patient acceptance than HNS. The improvement in AHI with HNS, as shown in the Stimulation Therapy for Apnea Reduction (STAR) trial, is similar to the improvement in AHI following MMA. Another subgroup includes appropriately selected adolescents with OSA and Down Syndrome who have difficulty in using CPAP. The following patient selection criteria are based on information from clinical study populations and clinical expert opinion.

- Age greater than or equal to 22 years in adults or adolescents with Down Syndrome age 10 to 21; AND
- Diagnosed moderate to severe OSA (with less than 25% central apneas); AND
- CPAP failure or inability to tolerate CPAP; AND
- Body mass index less than or equal to 32 kg/m^2 in adults; AND
- Favorable pattern of palatal collapse

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Sleep Medicine (AASM)

The American Academy of Sleep Medicine (AASM, 2021) published practice guidelines on when to refer individuals for surgical modifications of the upper airway for OSA.[47] These guidelines replaced the 2010 practice parameters for surgical modifications.[48] The AASM guidelines note that PAP is the most efficacious treatment for OSA, but effectiveness can be compromised when

patients are unable to adhere to therapy or obtain an adequate benefit, which is when surgical management may be indicated. The AASM guideline recommendations are based on a systematic review and meta-analysis of 274 studies of surgical interventions, including procedures such as UPPP, modified UPPP, MMA, tongue base suspension, and HNS.[49] The systematic review deemed most included data of low quality, consisting of mostly observational data. The AASM strongly recommends that clinicians discuss referral to a sleep surgeon with adults with OSA and BMI <40 kg/m2 who are intolerant or unaccepting of PAP. Clinically meaningful and beneficial differences in nearly all critical outcomes, including a decrease in excessive sleepiness, improved quality of life, improved AHI or RDI, and sleep quality, were demonstrated with surgical management in patients 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, as 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 Pediatrics

The American Academy of Pediatrics (2012) published a clinical practice guideline on the diagnosis and management of childhood OSA.[50] The Academy indicated that if a child has OSA, a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery, the clinician should recommend adenotonsillectomy as first line treatment. The Academy recommended that patients should be referred for CPAP management if symptoms/signs or objective evidence of OSA persists after adenotonsillectomy or if adenotonsillectomy is not performed. Weight loss was recommended in addition to other therapy if a child or adolescent with OSA is overweight or obese (defined as BMI greater than 95th percentile).

American Academy of Otolaryngology - Head and Neck Surgery

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS; 2021) has a position statement on surgical management of OSA.[51] Procedures AAO-HNS supported as effective and not considered investigational when part of a comprehensive approach in the medical and surgical management of adults with OSA 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

In a 2021 position statement, AAO-HNS supported HNS as an effective second-line treatment of moderate-to-severe OSA.[52]

American Society for Metabolic and Bariatric Surgery

The American Society for Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA.[53] The guideline indicated that OSA is strongly associated with obesity, with the incidence of OSA in the morbidly obese population reported as between 38% and 88%. The Society recommended bariatric surgery as the initial treatment of choice for OSA in this population, besides CPAP, as opposed to surgical procedures directed at the mandible or tissues of the palate. The updated 2017 guidelines reaffirmed these recommendations.[54]

National Institute for Health and Care Excellence

The NICE 2017 guidance concluded that evidence on the safety and efficacy of HNS is limited in quantity and quality, and the procedure should only be used in the context of a clinical trial.[55]

Medicare National Coverage

The Centers for Medicare & Medicaid Services (CMS; 2001) published a decision memorandum that addressed how to define moderate to severe OSA as a guide for a coverage policy for CPAP.[56] Because surgical approaches are considered when CPAP fails, the CMS policy was adapted to this policy on the surgical management of OSA. The CMS review of the literature suggested that there is a risk of hypertension with an AHI or RDI of at least 15 events per hour, and thus treatment is warranted for patients without any additional signs and symptoms. For patients with an AHI or RDI between 5 and 14 and associated symptoms, CMS concluded that the data from RCTs have demonstrated improved daytime somnolence and functioning in those treated with CPAP.

There is no national coverage determination for HNS.

Regulatory Status

The regulatory status of minimally invasive surgical interventions is shown in **Table 3**.

Table 3. Minimally Invasive Surgical Interventions for Obstructive Sleep Apnea

Interventions	Devices (predicate or prior name)	Manufacturer (previous owner)	Indication	PMA/ 510(k)	Year	FDA Product Code
Laser-assisted uvulopalatoplasty (LAUP)	Various					
Radiofrequency ablation	Somnoplasty		Simple snoring and for the base of the tongue for OSA	K982717	1998	GEI

Interventions	Devices (predicate or prior name)	Manufacturer (previous owner)	Indication	PMA/ 510(k)	Year	FDA Product Code
Palatal Implant	Pillar Palatal Implant	Pillar Palatal (Restore Medical/ Medtronic)	Stiffening the soft palate which may reduce the severity of snoring and incidence of airway obstructions in patients with mild to moderate OSA	K040417	2004	LRK
Tongue base suspension	AIRvance (Repose)	Medtronic	OSA and/or snoring. The AIRvance TM Bone Screw System is also suitable for the performance of a hyoid suspension	K122391	1999	LRK
Tongue base suspension	Encore (PRELUDE III)	Siesta Medical	Treatment of mild or moderate OSA and/or snoring	K111179	2011	ORY

Interventions	Devices (predicate or prior name)	Manufacturer (previous owner)	Indication	PMA/ 510(k)	Year	FDA Product Code
Hypoglossal nerve stimulation (HNS)	Inspire II Upper Airway Stimulation	Inspire Medical Systems	Patients greater than or equal to 18 years with AHI greater than or equal to15 and less than or equal to100 who have failed (AHI >15 despite CPAP usage) or cannot tolerate (<4 h use per night for greater than or equal to5 nights per week) CPAP and do not have complete concentric collapse at the soft palate level. Patients between ages 18 and 21 should also be contraindicated for or not effectively treated by adenotonsillectomy Inspire is also indicated in pediatric patients	P130008-S039	2014	MNQ
Hypoglossal nerve stimulation	aura6000	LivaNova (ImThera Medical)		IDE	2014	
Hypoglossal nerve stimulation	Genio	Nyxoa		European CE Mark	2019	

AHI: Apnea/Hypopnea Index; CPAP: continuous positive airway pressure; IDE: investigational device exemption; LAUP: Laser-assisted uvulopalatoplasty; OSA: obstructive sleep apnea.

The expanded indication for HNS in patients aged 18 to 21 was based on patients with Down Syndrome and is contingent on a post-approval study of the Inspire UAS in this age group. The

post-approval study will be a multicenter, single-arm, prospective registry with 60 pediatric patients age 18 to 21. Visits will be scheduled at pre-implant, post-implant, 6 months, and yearly thereafter through 5 years.

In June of 2023, the FDA expanded the indications in the premarket approval supplement for the Inspire HNS (P130008/SS090) for use to OSA patients with an upper limit baseline AHI to 100 (increase from less than or equal to 65 to less than or equal to 100) and increased the upper limit body mass index (BMI) warning to 40 (increase from less than or equal to32 to less than or equal to 40.

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History

Date	Comments
01/11/11	New Policy. Add to Surgery Section - This policy is held for notification subsequent to provider notification of 2.01.503. It will be effective 9/1/11.
09/1/11	This new policy is now effective pursuant to release of notification hold of 2.01.503.
06/26/12	Replace policy. Policy updated with literature search through February 2012; references added and reordered; policy statements unchanged. ICD-10 codes added to policy. AHI or RHI events clarified to be 5 – 14; does not change criteria but makes the policy statement more clear.
09/25/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
10/19/12	Update Related Policies – Add 1.01.524.
07/24/13	Replace policy. Policy updated with literature search through April 17, 2013; policy statements unchanged.
10/16/13	Update Related Policies. Change title to policy 2.01.503.
03/11/14	Coding Update. Codes 27.64 and 29.4 were removed per ICD-10 mapping project; these codes are not utilized for adjudication of policy.
04/18/14	Update Related Policies. Add 9.02.501.
07/14/14	New PR policy 7.01.554 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome, replacing 7.01.101. Medically necessary criteria for OSA diagnosis expanded to include a threshold of an AHI of 15-30 events as a specific criterion. When the AHI is 5-15, an additional requirement of documentation to evidence: stroke, hypertension, ischemic heart disease; or, symptoms of impaired cognition/mood disorder/insomnia; or, Epworth sleep scale greater than 10 or MSLT less than 6 to evidence daytime sleepiness; or, more than 20 episodes of desaturation; or obesity (BMI over 35). When the AHI is greater than 30, the patient must be able to tolerate PAP or it must be contraindicated. Criteria for children updated to an apneic/hypopneic index (AHI) greater than 1.5. ICD-9 and ICD-10 procedure and diagnosis codes removed; they are not utilized in adjudication. Policy effective subsequent to 2.01.532 effective October 23, 2014. Added investigational policy statement for implantable hypoglossal nerve stimulators.
10/23/14	Reissue policy as updates are now effective; reference to previous version removed.
06/17/15	Annual Review. No change to policy statements. Informational CPT codes removed; these are not reviewed.
02/09/16	Annual Review. Policy updated with literature review through January 2016; reference 31 added; policy statements unchanged.
03/01/17	Annual Review, approved February 14, 2017. Policy updated with literature review through October 4, 2016; references 17-20 added. Coding update; added codes, including new CPT codes effective 1/1/17. No change to policy statements.

Date	Comments
03/30/17	Policy moved into new format; no change to policy statements.
12/01/17	Interim Review, approved November 9, 2017. Policy updated with literature review through July 20, 2017; reference 27 added, references 26,28, 29, 31, updated. Policy statements unchanged. Removed CPT code 0468T.
01/01/18	Removed Related Policies 1.01.524, 2.01.503, and 2.01.532 as they were archived.
03/01/18	Interim Review, approved February 27, 2018. Note added that this policy has been revised. Added Surgery Site of Service criteria, which becomes effective June 1, 2018.
06/01/18	Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.
01/01/19	Annual Review, approved December 13, 2018. Policy approved with no changes at this time; however, the approval included the addition of future edits to the policy statements.
02/01/19	Annual Review, approved January 8, 2019. Policy updated with literature review through October 2018; References added, and some references removed. Hypoglossal nerve stimulation is considered medically necessary under specified conditions.
05/01/19	Minor update, clarified Site of Service requirements.
09/01/19	Interim Review, approved August 6, 2019. Policy updated with literature review through April 2019; references added. The indication for hypoglossal nerve stimulation changed to apnea/hypopnea index of greater than or equal to15 from greater than or equal to 20 for alignment with the Food and Drug Administration-approved indication. Policy statements otherwise unchanged. Added CPT code 21685.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
05/06/20	Interim Review, approved May 5, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
06/01/20	Policy 7.01.554 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome deleted and replaced with policy 7.01.101 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome, approved May 12, 2020, effective June 1, 2020. Policy statements remain unchanged except for clarifying minor edits; this is effectively a policy renumber.
09/01/20	Interim Review, approved August 4, 2020. Policy updated with literature review through May, 2020; references added. Policy statements unchanged. Removed CPT codes 21685, 41512, 41530, 42950 and S2080.
11/01/20	Coding update. Added HCPCS code C9727.

Date	Comments
09/01/21	Annual Review, approved August 3, 2021. Policy updated with literature review through April 26, 2021; references added. Policy statements unchanged. Added CPT codes 21685, 41512, 41530 42950 and HCPC code S2080.
01/01/22	Coding update, added new CPT code 64582, 64583, & 64684 and updated description of CPT code 64568.
08/01/22	Interim Review, approved July 12, 2022. Changed criteria statement for hypoglossal nerve stimulation for CPAP failure from residual AHI greater than or equal to20 to greater than or equal to 15 for consistency with other policies.
09/01/22	Annual Review, approved August 8, 2022. Policy updated with literature review through May 8, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Policy statements unchanged.
09/01/23	Annual Review, approved August 21, 2023. Policy updated with literature review through April 26, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
11/01/23	Interim Review, approved October 10, 2023. Policy criteria for HNS in adults with OSA changed from BMI less than or equal to 32kg/m^2 to less than or equal to 40 kg/m^2 to align with expanded FDA indication that was approved 6/8/2023.Other minor edits made to policy criteria; intent unchanged.
01/01/24	Interim Review, approved December 26, 2023. References added. Endoscopically assisted nasomaxillary expansion added to list of minimally invasive surgical procedures for the treatment of OSA that are considered investigational.
10/01/24	Policy 7.01.101 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome deleted and replaced with 7.01.554 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome, approved September 10, 2024. Policy updated with literature review through May 6, 2024; references added. Policy statements for BMI with HNS updated to align with current evidence (BMI criteria changed from less than or equal to40 to less than or equal to35 kg/m^2) as well as age for use in adults changed from greater than or equal to22 to greater than or equal to18 and in individuals with Down syndrome age changed from 10 to 21 to 13 to 18. Added HCPCS codes C1767 and C1778 back to policy.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.