



Medical Coverage Policy

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Surgical Treatments for Obstructive Sleep Apnea

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Overview

This Coverage Policy addresses surgical treatments for obstructive sleep apnea (OSA).

Coverage Policy

In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage of the treatment of obstructive sleep apnea and other sleep disorders varies across plans. Refer to the customer's benefit plan document for coverage details.

Drug-induced sleep endoscopy (DISE) is considered medically necessary for the evaluation of upper airway surgery in an adult when EITHER of the following is met:

- persistent obstructive sleep apnea (OSA) defined as BOTH of the following
 - criteria for positive airway pressure (PAP) met and documentation that demonstrates PAP treatment failure defined as an inability to eliminate OSA (AHI > 15); OR PAP intolerance defined as inability to use PAP > 4 hours of use per night, 5 nights per week; OR unwillingness to use PAP (e.g., a patient returns the PAP system after attempting to use it)
 - a mandibular repositioning appliance (MRA) or tongue-retaining appliance has been considered and found to be ineffective or undesirable
- persistent OSA after surgical intervention to treat OSA

DISE is considered medically necessary in an adolescent aged 13-18 with Down syndrome to evaluate the appropriateness of a U.S. Food and Drug Administration (FDA)-approved implantable upper airway hypoglossal nerve stimulation device.

DISE is considered medically necessary in a child for EITHER of the following:

- evaluation of persistent OSA after surgical intervention to treat OSA
- evaluation of suspected OSA, as evidenced by observed restlessness with sleep, apneic periods, sleep disturbance, snoring, sleepiness upon awakening or during daytime, when performed in conjunction with other surgery (e.g., tonsillectomy, adenoidectomy, nasal or sinus surgery).

Uvulopalatopharyngoplasty (UPPP) is considered medically necessary for the treatment of OSA when ALL of the following criteria are met:

- demonstrated narrowing or collapse of the retropalatal region (soft palate, uvula, tonsils, posterior pharyngeal wall) as a source of airway obstruction

- criteria for PAP met and documentation that demonstrates PAP treatment failure defined as an inability to eliminate OSA (AHI > 15); OR PAP intolerance defined as inability to use PAP > 4 hours of use per night, 5 nights per week; OR unwillingness to use PAP (e.g., a patient returns the PAP system after attempting to use it)
- for OSA in an adult, consideration has also been given to use of mandibular repositioning appliance (MRA) or tongue-retaining appliance

Uvulectomy as a stand-alone procedure for the treatment of OSA is considered experimental, investigational or unproven. (Note: this Coverage Policy is not intended to address uvulectomy performed for other indications [e.g., acute inflammation/angioedema of the uvula, a globus sensation, coughing, or gagging symptoms due to elongated uvula]).

Multi-level or stepwise surgery (MLS) (e.g., UPPP and/or genioglossus advancement and hyoid myotomy [GAHM], maxillary and mandibular advancement osteotomy [MMO]) as a combined procedure or as stepwise multiple procedures is considered medically necessary for the treatment of OSA when ALL of the following criteria are met:

- narrowing of multiple sites in the upper airway
- criteria for PAP met and documentation that demonstrates PAP treatment failure defined as an inability to eliminate OSA (AHI > 15); OR PAP intolerance defined as inability to use PAP > 4 hours of use per night, 5 nights per week; OR unwillingness to use PAP (e.g., a patient returns the PAP system after attempting to use it)
- in an adult, a mandibular repositioning appliance (MRA) or tongue-retaining appliance has been considered and found to be ineffective or undesirable

Maxillomandibular advancement is considered medically necessary for the treatment of severe OSA when ALL of the following criteria are met:

- criteria for PAP met and documentation that demonstrates PAP treatment failure defined as an inability to eliminate OSA (AHI > 15); OR PAP intolerance defined as inability to use PAP > 4 hours of use per night, 5 nights per week; OR unwillingness to use PAP (e.g., a patient returns the PAP system after attempting to use it)
- in an adult, a mandibular repositioning appliance (MRA) or tongue-retaining appliance has been considered and found to be ineffective or undesirable
- individual has craniofacial disproportion or deformities

A U.S. Food and Drug Administration (FDA)-approved implantable upper airway hypoglossal nerve stimulation device is considered medically necessary for the treatment of moderate to severe OSA in an individual ≥ age 18 when ALL of the following criteria are met:

- AHI on PSG* of ≥ 15-and ≤100 events per hour with < 25% central + mixed apneas
- body mass index (BMI) ≤ 40
- absence of a complete concentric collapse at the soft palate level on drug induced sleep endoscopy
- documentation that demonstrates EITHER positive airway pressure (PAP) treatment failure defined as an inability to eliminate OSA (AHI ≥ 15); OR PAP intolerance defined as inability to use PAP > 4 hours of use per night, 5 nights per week; OR unwillingness to use PAP (e.g., a patient returns the PAP system after attempting to use it)

A U.S. Food and Drug Administration (FDA)-approved implantable upper airway hypoglossal nerve stimulation device is considered medically necessary for the

treatment OSA in a pediatric individual age 13-18 years with Down syndrome and AHI >10 and < 50 when ALL of the following criteria are met:

- absence of complete concentric collapse at the soft palate level
- contraindicated for, or not effectively treated by adenotonsillectomy
- confirmed to have failed, or cannot tolerate, PAP therapy despite attempts to improve compliance
- all other alternative/adjunct therapies have been considered

The replacement of a remote that is used with an FDA-approved implantable upper airway hypoglossal nerve stimulation device is considered medically necessary when there is documentation confirming that the remote is malfunctioning and is no longer under warranty.

NOTE: Off-the-shelf batteries, used in the remote for the hypoglossal nerve stimulation device, are generally considered not medically necessary because they are not primarily medical in nature.

***Note: Criteria for the HSAT and PSG testing pre- and post- upper airway hypoglossal nerve stimulator implantation are covered in the Sleep Disorders Diagnosis and Treatment Guidelines.**

ADDITIONAL PROCEDURES/SERVICES

The following procedures for the treatment of OSA are considered experimental, investigational or unproven:

- atrial overdrive pacing
- cautery-assisted palatal stiffening operation (CAPSO)
- injection Snoreplasty
- Pillar™ Palatal Implant System
- radiofrequency volumetric tissue reduction (RFVTR) of the soft palate, uvula, or tongue base (e.g., Coblation®, Somnoplasty®)
- tongue-base suspension (e.g., AIRvance™ System, ENCORE™ Tongue Suspension System)
- tongue implant (e.g., ReVent System)
- transpalatal advancement pharyngoplasty

The treatment of snoring alone by any method is considered not medically necessary.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Obstructive sleep apnea (OSA) is an independent risk factor for hypertension, heart failure, and stroke. There is strong evidence that Black individuals are disproportionately impacted by these

cardiovascular diseases. Early identification and treatment of underlying OSA in this population would therefore provide significant benefit; early evidence suggests that OSA treatment could contribute to reducing the disparity in hypertension between Black and White individuals. Thornton et al. (2022) evaluated data from an urban academic sleep center, assessing for racial disparities in OSA characteristics at the time of initial diagnosis. The analysis included 890 newly diagnosed patients. Black men were underrepresented in the sleep lab, consisting of only 15.8% of the cohort, but had the most severe OSA, with a mean AHI of 52.4 ± 39.4 per hour compared with 39.0 ± 28.9 in White men. The authors concluded that at the time of clinical diagnosis, Black men have greater disease severity, suggesting delayed diagnosis. In addition, the greater burden of classic OSA symptoms suggests the delayed diagnosis is not due to atypical presentation.

OSA affects up to 80% of children with Down syndrome, compared to approximately 5% of healthy children. Factors contributing to the prevalence of OSA in this population include generalized hypotonia, macroglossia, facial hypoplasia, small tracheal diameter, and lingual tonsillar hypertrophy. Medical comorbidities, including hypothyroidism, gastroesophageal reflux, aspiration, recurrent respiratory infections and seizures, contribute to OSA. Management of OSA in children with Down syndrome is similar to that of other individuals. Consequences of untreated OSA in children may include inattention and behavioral problems, daytime sleepiness, failure to thrive, and cardiovascular consequences (Liu et al., 2022, Seither et al., 2023).

Adenotonsillectomy is considered the treatment of choice in children but is not effective in approximately two thirds of children with Down syndrome. Many patients require CPAP support following adenotonsillectomy, but it is poorly tolerated. Compliance often is not adequate to meet treatment needs because of discomfort, inconvenience, cognitive delay and frequent presence of sensory processing disorders. Hypoglossal nerve stimulation has recently emerged as a treatment option for adolescents with Down syndrome who meet selection criteria (Liu et al., 2022, Stenerson et al., 2021).

General Background

Obstructive sleep apnea (OSA) is a disorder characterized by obstructive apneas and hypopneas due to repetitive collapse of the upper airway during sleep. Untreated OSA is associated with symptoms of excessive daytime sleepiness, metabolic dysfunction, impaired daytime function and an increased risk of cardiovascular disease and mortality. For most adults, first-line therapy for OSA consists of behavioral modification, including weight loss if appropriate, and positive airway pressure (PAP) therapy. Generally, surgical treatment of OSA is reserved as a second-line therapy for OSA, either as secondary therapy in individuals with OSA who cannot adhere to continuous positive airway pressure (CPAP) or as adjunctive therapy along with CPAP or an oral appliance. The choice among various second-line options depends on the severity of the OSA and the patient's anatomy, risk factors and preferences. Although surgical treatment for OSA provides long-term benefits in selected individuals, complete elimination of OSA is often not achieved. Various surgical procedures have generally not been compared directly with one another, and surgical decisions are individualized based on patient anatomy and surgeon preferences (Weaver and Kapur, 2021).

Procedures

Surgical treatment of OSA includes multiple procedures and approaches that enlarge and/or stabilize the upper airway. These procedures can be categorized as nasal, upper pharyngeal, lower pharyngeal and global upper airway procedures. Careful patient and procedure selection, especially related to the anatomy, physiology, and function of the upper aerodigestive tract, and perioperative risk management, are key considerations in the surgical evaluation of patients with OSA (Weaver and Kapur, 2021).

Upper pharyngeal procedures: The goal of upper pharyngeal procedures in the context of OSA is to relieve upper pharyngeal obstruction. If other obstructing areas are present (e.g., lower pharyngeal obstruction), additional treatment is required (e.g., lower pharyngeal procedures, oral appliance, or CPAP). Examples of upper pharyngeal procedures include:

- **Uvulopalatopharyngoplasty (UPPP):** UPPP is the most common surgical procedure for OSA since upper pharyngeal obstruction is the most common anatomic airway abnormality. UPPP is a surgical reconstructive procedure that involves reducing, tightening and/or repositioning the soft palate and related oropharyngeal structures with the goal of improving the airway while asleep. It often includes reduction, removal, or reconfiguration of the uvula. There are many variations of this procedure including: uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty and relocation pharyngoplasty. Each procedure focuses on correcting pharyngeal airway compromise. Some of the variants may be combined to address complicated palatal obstruction. Usually a palatine tonsillectomy is performed simultaneously if the tonsils are still present. Selection of the optimal UPPP variant depends on individual anatomy and functional examination of the upper pharynx and palate.
- **Tonsillectomy and Adenoidectomy:** Tonsillectomy is part of UPPP when the palate procedure is performed simultaneously. Isolated tonsillectomy is reserved for individuals with isolated palatine tonsillar hypertrophy without palatal abnormalities. Adenoidectomy is performed with tonsillectomy or in isolation.

Lower pharyngeal and laryngeal procedures: The goal of lower pharyngeal and laryngeal procedures in the context of OSA is to relieve a variety of types of obstruction or collapse in these areas. These procedures are typically used in conjunction with surgery to relieve upper pharyngeal obstruction. There are multiple proposed procedures for improving the lower pharyngeal airway (e.g., tongue reduction, tongue advancement/stabilization and epiglottis correction). Each procedure is focused on a specific target area or problem. Some procedures occur in the lower pharyngeal airway (e.g., midline glossectomy) and others occur at adjacent sites with effects on the lower pharyngeal airway (e.g., genioglossus advancement).

Tongue reduction procedures are performed by multiple methods including lasers, electrocautery and radiofrequency. Transoral robotic surgery for tongue reduction relies on electrocautery. Radiofrequency tongue reduction is a minimally invasive procedure which creates a submucosal scar that stiffens the tissue and reduces tongue size. Lingual tonsillectomy improves the airway by removing obstructing lingual tonsil tissue identified on indirect mirror exam or flexible laryngoscopy.

Several procedures are proposed to advance or stabilize the tongue base and pharyngeal musculature. These procedures are used individually or in combination, depending on the location and severity of tongue base obstruction. Examples include:

- **Genioglossus advancement** involves creating an osteotomy around the genial tubercle on the anterior mandible and advancing it 10-15 mm forward without moving the teeth.
- **Mandibular advancement** moves forward most of the anterior mandible, including the genial tubercle, other sites of tongue attachment and the lower teeth.
- **Hyoid suspension** advances and stabilizes the hyoid bone to the thyroid cartilage or to the mandible. The hyoid bone is attached to the base of the tongue and other pharyngeal musculature. Therefore, stabilization of the hyoid bone can help stabilize the lower tongue base and pharynx.
- **Tongue suspension** anchors a suture or tether to the anterior mandible, creating a tongue base sling.

Global upper airway procedures: Global upper airway procedures include three procedures, each with specific indications that are proposed to improve the upper and lower pharyngeal airway globally or bypass the upper airway; they are not site-directed. Among the various types of surgical procedures, maxillomandibular advancement and tracheotomy are generally associated with the greatest degree of improvement in polysomnographic parameters of OSA. Global upper airway procedures include:

- **Maxillomandibular advancement:** Maxillomandibular advancement projects the entire lower facial skeleton and attached soft tissues forward. This is a major operation that is typically reserved for patients with persistent, significant OSA following other site-directed surgical treatments or with baseline maxillary or mandibular hypoplasia.
- **Tracheotomy:** Tracheotomy bypasses the entire upper airway. An OSA tracheotomy cannula is usually used instead of a standard tracheotomy tube. The cannula is smaller, more comfortable and easier to manage than a standard tracheotomy tube. Individuals can eat and speak normally with the cannula capped during waking hours and can breathe easily with the cannula open during sleeping hours. Most patients wish to avoid tracheotomy, so it is typically reserved for patients with severe OSA who fail CPAP therapy and who cannot tolerate upper airway reconstruction because of critical comorbidities.
- **Upper airway stimulation:** Upper airway stimulation via an implantable neurostimulator device activates the protrusion muscles of the tongue via the hypoglossal nerve to open the lower pharyngeal airway.

Nasal procedures: The utility of nasal procedures in the context of OSA is to relieve nasal obstruction as an adjunctive measure to improve outcomes with CPAP, an oral appliance or other surgery. It is recommended that nasal procedures not be used as a stand-alone therapy for treatment of moderate or severe OSA. Examples of nasal procedures include:

- **Turbinate reduction:** Turbinate reduction reduces obstruction caused by inferior turbinate hypertrophy, which is a common cause of nasal obstruction, especially related to recumbent position. The goal of turbinate surgery is to reduce size without compromising mucosal function. Turbinate mucosa is important for humidifying, warming and filtering air. Several methods are available for turbinate reduction including: radiofrequency, turbinate outfractures, submucous resection, intramural cauterization and cryotherapy
- **Septoplasty, nasal valve surgery and rhinoplasty.** (See Medical Coverage Policy Rhinoplasty, Vestibular Stenosis Repair and Septoplasty for information on treatment of OSA with these procedures).
- **Endoscopic procedures:** Concha bullosae (enlarged middle turbinates with an indwelling sinus cell) and nasal polyposis are corrected with endoscopic nasal procedures.

Epiglottis procedures: Epiglottis procedures treat epiglottis collapse and obstruction. Partial epiglottidectomy shortens the epiglottis to prevent critical collapse. Epiglottopexy stabilizes the base of the epiglottis to the tongue base to prevent retroflexion or collapse. Hyoid suspension stabilizes the epiglottis indirectly through its attachment to the hyoid bone via the hyoepiglottic ligament. Some of these epiglottis procedures require a neck incision.

Literature Review

Drug-Induced Sleep Endoscopy (DISE): DISE is a sedative-induced sleep nasopharyngoscopy that assists in evaluating the lumen of the nasal passages, oropharynx and vocal cords. A flexible fiberoptic laryngoscope is used during anesthetically simulated sleep with preservation of spontaneous respiration. Studies have evaluated DISE for upper airway obstruction, airway luminal changes in patients with OSA, predication of oral appliance and hypoglossal nerve stimulation outcomes, and the effects of mandibular repositioning devices, weight loss, or UPPP on airway caliber (Schwab, 2022; Kirkham and Garetz, 2021).

Saniasiaya and Kulasegarah (2020) conducted a systematic review to determine the outcome of DISE directed surgery in children with obstructive sleep apnea. Seven articles (n=996), including retrospective, case-control and prospective studies, were included. Following DISE, 295 patients (30%) had changes in their surgical decision and 86% underwent multilevel surgery based on DISE.

Albdah et al. (2019) conducted a systematic review and meta-analysis to assess the ability of DISE to change therapeutic decisions through the identification of obstruction sites in patients with OSA. Nine studies (n=1,247; 69.2% males, 59.7% children), including one retrospective analysis, one case-control study and seven prospective cohort studies, were included. Therapeutic decisions changed in 43.69% of patients with significantly higher rates of change in adults than those in children ($p=0.001$), midazolam-based DISE protocols ($p<0.001$), and DISE versus awake endoscopy ($p=0.02$). Changes at uvular and palatal sites were more frequent in adults and at the tonsils in children.

Uvulopalatopharyngoplasty (UPPP): Franklin et al. (2009) conducted a systematic review to evaluate the efficacy and adverse effects of surgery for snoring and OSA. The review included four randomized controlled trials of surgery vs. either sham surgery or conservative treatment in adults. The trials included outcome measures of daytime sleepiness, quality of life, AHI, and snoring. There was no significant effect on daytime sleepiness and quality of life after laser-assisted uvulopalatoplasty (LAUP). The AHI and snoring were reduced in one trial after LAUP but not in another. A total of 45 observational studies were also reviewed to evaluate adverse effects following surgical treatment. Persistent side-effects occurred after uvulopalatopharyngoplasty (UPPP) and uvulopalatoplasty (UPP), with difficulty swallowing, globus sensation, and voice changes commonly observed.

A Cochrane systematic review assessed the results of any surgery in the treatment of OSA in adults (Sundaram, et al., 2005). UPPP was one of several procedures evaluated. The authors concluded that available studies do not provide evidence to support the use of surgery in OSA because overall significant benefit has not been demonstrated. Long-term follow-up of patients who undergo surgical treatment is required to determine whether surgery is curative or whether the signs and symptoms of OSA tend to recur, requiring further treatment.

Sher et al. (1996) conducted a systematic literature review with meta-analysis to provide an overview of the surgical treatment of OSA to provide the basis for the AASM practice parameters on this subject. Studies included in the meta-analysis provided preoperative and postoperative PSG data on at least nine patients treated with UPPP for OSA. Analysis of the UPPP studies revealed that this procedure is, at best, effective in treating less than 50% of patients with OSA. AASM practice parameters based on this review state that UPPP, with or without a tonsillectomy, may be appropriate for patients with narrowing or collapse in the retropalatal region. The recommendations also state that effectiveness of UPPP is variable, and the procedure should only be performed when nonsurgical treatment options, such as PAP, have been considered.

The recommendation for UPPP in the 2010 AASM practice parameters for surgical modification of the upper airway (Aurora, et al., 2010) states that UPPP does not reliably normalize the AHI in moderate to severe OSA; patients with severe OSA should therefore initially be offered PAP therapy, while those with moderate OSA should initially be offered either PAP therapy or an oral appliance. This recommendation differs from the previously published guideline that recommended UPPP for patients with narrowing or collapse of the retropalatal area.

Uvulectomy: Uvulectomy has been proposed as a surgical treatment for snoring and mild obstructive sleep apnea. There are no well-designed studies in the peer-reviewed medical literature that evaluate uvulectomy for the treatment of obstructive sleep apnea. Based on the

available evidence, it is not possible to determine the safety and efficacy of this procedure compared to established medical and surgical treatment. Uvulectomy performed as a separate procedure is not addressed in relevant published specialty society guidelines.

(Note: This Coverage Policy is not intended to address uvulectomy when performed for other indications [e.g., acute inflammation/angioedema of the uvula]).

Multi-Level or Stepwise surgery (MLS): This category includes a wide array of combined procedures that address narrowing of multiple upper airway sites. MLS often consists of phase I, utilizing UPPP and/or genioglossus advancement and hyoid myotomy (GAHM). Phase II procedures, consisting of maxillary and mandibular advancement osteotomy (MMO), may be considered for patients who fail phase I surgeries (Aurora, et al., 2011).

AASM Practice Parameters for the Surgical Modification of the Upper Airway for OSA (Aurora, et al, 2010) discussed above state that use of multi-level or stepwise surgery (MLS), as a combined procedure or as stepwise multiple operations, is acceptable in patients with narrowing of multiple sites in the upper airway, particularly if they have failed UPPP as a sole treatment. Although a large volume of literature addressing MLS exists, the evidence is of low quality, consisting of observational case series or comparative studies without randomization. While a multilevel approach may eventually result in significant improvement in AHI, available data are heterogeneous, clinical outcomes such as cardiovascular events are not well studied, and multiple procedures could be associated with increased morbidity and mortality.

Maxillomandibular Advancement (MMA): Maxillomandibular advancement is a surgical procedure that involves the simultaneous advancement of the maxilla and mandible through sagittal split osteotomies. The procedure provides enlargement of the retrolingual airway, and some advancement of the retropalatal airway (Aurora, et al., 2010).

Holty and Guilleminault (2010) conducted a systematic review and meta-analysis of 22 studies (n=627 patients) to evaluate the clinical efficacy and safety of maxillomandibular advancement for the treatment of OSA. The mean AHI decreased from 63.9/hour to 9.5/hour ($p<0.001$) following surgery. The pooled surgical success and cure ($AHI<5$) rates were 86.0% and 43.2%, respectively. Younger age, lower preoperative weight and AHI, and greater degree of maxillary advancement were predictive of increased surgical success. The major and minor complication rates were 1.0% and 31%, respectively. Long-term surgical success was maintained at a mean follow-up of 44 months. Statistically significant improvements in quality of life measures, OSA symptomatology (i.e., excessive daytime sleepiness) and blood pressure control were reported after MMA. The authors concluded that MMA appears to be a safe and highly effective treatment for OSA, but further research is needed to assess clinical outcomes of MMA more thoroughly in long-term cohort studies, and to identify which OSA patients would benefit most from MMA.

AASM Practice Parameters for the Surgical Modification of the Upper Airway for OSA (Aurora, et al., 2010), discussed above, state that MMA is indicated for surgical treatment of severe OSA in patients who cannot tolerate or who are unwilling to adhere to positive airway pressure therapy, or in whom oral appliances, which are more often appropriate in mild and moderate OSA patients, have been considered and found ineffective or undesirable. The evidence was considered to be very low quality, consisting of nine case series, but did tend to demonstrate consistent effectiveness in severe OSA. In the published series, AHI was reduced to at least 10/hour in most patients, but PAP remains more effective in normalizing AHI, and improvement in other measures such as sleepiness and quality of life are well supported for PAP but are lacking for MMA. PAP or oral appliance therapy therefore should be suggested ahead of MMA in appropriate candidates.

Traditional “stepped” care frequently utilizes MMA as a final approach for surgical treatment of OSA, but MMA may be considered as an initial or sole approach in treating OSA. The authors recommended multidisciplinary evaluation to identify which patients would benefit from MMA as initial or sole therapy. There is a need for further clarification regarding the relative risks and benefits of MMA compared with other treatment modalities

Tracheostomy: AASM practice parameters (Aurora, et al., 2010) state that tracheostomy has been shown to be an effective single intervention to treat OSA. This operation should be considered only when other options do not exist, have failed, are refused, or when this operation is deemed necessary by clinical urgency. This recommendation is considered an Option; although tracheostomy is nearly always successful in bypassing the upper airway obstruction and normalizing AHI, it is not recommended as primary therapy based on placing a high value on patient safety, autonomy, and quality of life.

Implanted Upper Airway Hypoglossal Nerve Stimulation Devices: Diminished muscle activity or tone in the upper airway during sleep can cause the tongue to slip from its normal position and occlude the pharynx, thereby obstructing the airway, creating the conditions for OSA. Implantable upper airway stimulation devices have been proposed to treat moderate to severe OSA. The devices provide mild electrical stimulation to the medial branch of the hypoglossal nerve which produces selective motor stimulation of the muscle fibers that draw the tongue forward via activation of the major muscle responsible for protruding the tongue. It has been proposed that this results in improvement of upper airway obstruction, ideally without arousal or patient discomfort (Hayes, 2018).

Hypoglossal nerve stimulation (HGNS) devices are implanted by a pulmonologist, thoracic surgeon, or other qualified physician. Hypoglossal nerve monitoring may occur during the procedure. Hospitalization is generally not required for device implantation. The standard of care for patients with moderate to severe OSA is CPAP. Oral appliances may also be considered for patients with less severe conditions or for those who are intolerant of CPAP. Proposed surgical procedures can include tracheostomy, nasal reconstruction, Uvulopalatopharyngoplasty (UPPP), and tongue advancement or reduction (Hayes, 2018; Vanderveken, et al., 2017).

Inspire® Upper Airway Stimulation (UAS) (Inspire Medical Systems Inc., Maple Grove, MN) received FDA approval through the PMA process on April 30, 2014 (P130008). The implanted components of the Inspire therapy system consist of the Inspire II implantable pulse generator, the stimulation lead, and the respiratory sensing lead model. When therapy is on, the Inspire system detects the patient’s respiratory effort and maintains 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 patient uses the Inspire Sleep Remote™ to turn therapy on before sleep and to turn therapy off on awakening.

The original approval order states that the device is used to treat a subset of patients aged 22 years or older with moderate to severe OSA ($AHI \geq 20$ and ≤ 65) who have failed or cannot tolerate positive airway pressure (PAP) treatments such as continuous positive airway pressure or bilateral positive airway pressure and who not have a complete concentric collapse at the soft palate level. PAP failure is defined as inability to eliminate OSA ($AHI >15$ despite PAP usage), and PAP intolerance is defined as:

- inability to use PAP (greater than five nights per week of usage; usage defined as greater than four hours of use per night, or
- unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).

A PMA supplement issued on June 23, 2017 (PMA 130008/S021) expanded the AHI range from 20-65 events per hour to 15-65 events per hour, and a subsequent supplement (PMA 130008/S39) expanded the indicated age from 22 to 18.

On June 8, 2023 (PMA supplement P130008/S090) indications for use were revised to include use in OSA patients with an upper limit baseline AHI of 100 (increase from ≤ 65 to ≤ 100) and the upper limit BMI warning was increased to 40 (increase from ≤ 32 to ≤ 40). This supplement states that the Inspire UAS is also indicated for use in pediatric patients ages 13 to 18 years with Down syndrome and AHI > 10 and < 50 who:

- do not have complete concentric collapse at the soft palate level
- are contraindicated for, or not effectively treated by, adenotonsillectomy
- have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance
- have followed standard of care in considering all other alternative/adjunct therapies

The FDA Labeling document for Inspire UAS (P130008) states contraindications for the use of Inspire UAS therapy include the following:

- Central + mixed apneas > 25% of the total apnea-hypopnea index (AHI)
- Any anatomical finding that would compromise the performance of upper airway stimulation, such as the presence of complete concentric collapse of the soft palate
- Any condition or procedure that has compromised neurological control of the upper airway
- Patients who are unable or do not have the necessary assistance to operate the sleep remote.
- Patients who are pregnant or plan to become pregnant. UAS has not been evaluated for safety or efficacy during pregnancy.
- Patients with an implantable device that may be susceptible to unintended interaction with the Inspire system. Consult the device manufacturer to assess the possibility of interaction.
- Patients who require magnetic resonance imaging (MRI) other than what is specified in the MRI conditional labeling.

The FDA warnings and precautions section of the Labeling documents states that data on BMI > 40 was not studied on a significant number of patients in post-market registries and clinical trials. Safety and effectiveness of Inspire UAS for the BMI>40 patient population is unknown at this time. Pediatric patients with Down syndrome and a BMI over the 95th percentile on the Centers for Disease Control and Prevention neurotypical growth curves have not been studied.

The Inspire UAS device generator, which includes the battery, may need to be replaced when the device nears the end of the battery life. Typical battery life is 10 years. Generator battery life depends on how often therapy is used and the therapy settings. Most generator batteries will last at least seven years. To replace the generator battery, requires replacing the entire generator. A surgical procedure is required. The Inspire Sleep Remote has a five year minimum life and runs on over-the-counter batteries. The Inspire warranty period for implanted products is three years. All other products have a warranty period of one year (Inspire, 2021).

Heiser, et al. (2022) compared hypoglossal nerve stimulation (HNS) to PAP treatment with outcome measures of sleepiness, AHI, and effectiveness. Of 227 patients treated consecutively, 126 could be matched 1:1 regarding age, BMI, and AHI. Of those 126 patients, 117 were treated with HNS and 110 received PAP therapy. PAP therapy was initiated as first-line treatment in patients newly diagnosed with OSA, while HNS was initiated as a second line treatment after failure or intolerance of PAP treatment. A clinically significant improvement in symptoms was seen in both groups at 12 months, but a greater improvement in ESS was seen in those treated with HNS (HNS: 8.1 ± 5.1 points vs. 3.9 ± 6.8 points; $p=0.042$). In both groups, mean post-treatment

AHI was significantly reduced (HNS: $8.1 \pm 6.3/h$; PAP $6.6 \pm 8.0/h$; $p < 0.001$). Adherence to treatment after twelve months was higher with HNS but was not statistically significant. The authors concluded that patients treated with HNS had significantly greater improvement with daytime sleepiness compared to PAP, while the mean reduction of AHI and overall effectiveness were comparable in both groups.

The Stimulation Therapy for Apnea Reduction (STAR) Trial (Strollo et al., 2014), a multi-center prospective cohort study, evaluated the use of HGNS in patients with moderate to severe OSA in who were intolerant to PAP or in whom PAP had failed ($n=126$). Patients were excluded if there was complete concentric collapse of the retropalatal airway during drug-induced sleep endoscopy. The primary outcome measures were AHI and oxygen desaturation index. At twelve months, 60% of participants achieved at least a 50% decrease in AHI. The median AHI decreased 68%, from 29.3 to 9.0 events/hour. The first 46 consecutive participants who were responsive to treatment were randomized to either continued therapy or withdrawal from therapy. At seven days, the AHI of the treatment group remained stable (mean 7.2-9 events/hour), while the mean AHI in the group withdrawn from treatment increased from 7.6 to 25.8 events/hour. Follow-up studies of participants in the STAR trial conducted at 18 months, 36 months, and five years indicated that the treatment effects (reduced AHI from baseline) were maintained. After five years, eight patients (6%) had device related complications requiring surgery to replace or remove the device. (Strollo et al., 2015; Woodson et al., 2016, Woodsen et al., 2018).

Published evidence evaluating HGNS for the treatment of OSA consists primarily of prospective and retrospective case series and registry data; it has not been evaluated in well-designed randomized controlled trials. Although the evidence is not robust, there is adequate evidence to support the safety and efficacy of HGNS for treatment of moderate to severe OSA in carefully selected patients who are intolerant of or unwilling to use PAP.

Down Syndrome

Children with Down syndrome are at increased risk of OSA because of soft tissue and skeletal alternations that lead to upper-airway obstruction. Although adenotonsillectomy is the treatment of choice, it is only effective in approximately one-third of cases. Many patients require PAP after surgery, but it is often poorly tolerated. The use of HNS has therefore been explored as a treatment option for individuals with Down syndrome.

Liu et al. (2022) conducted a systematic review and meta-analysis to evaluate HNS in adolescents with down syndrome and obstructive sleep apnea. Of 92 articles identified, nine (106 patients) studies met the inclusion criteria. The age of participants ranged from 10-21 years. With follow-up periods ranging from two to 58 months. The Yu cohort study described below was the largest of the studies. Six of the studies included sample sizes less than 10. The studies demonstrated that patients receiving HNS experienced a significant decrease in AHI (at least 50%). The pooled AHI was significantly lower in patients following treatment (mean AHI reduction 17.43 events/h, 95% confidence interval 13.98-20.88 events/h ($p < 0.001$).

Yu and associates (2022) published a prospective single group multicenter cohort with one year follow up. The objective was to evaluate the safety and effectiveness of upper airway stimulation for adolescent patients with Down syndrome (DS) and severe obstructive sleep apnea (OSA). The 42 subjects had Down syndrome, were between the ages of 10-22 years, had persistent severe OSA (AHI of 10 events per hour despite adenotonsillectomy), and had inability to tolerate nighttime PAP or tracheostomy dependence. Patients were excluded if they had a central apnea contribution $>25\%$; had a BMI $>95^{\text{th}}$ percentile on the CDC and Prevention neurotypical growth curves; had a medical condition that would require future MRI, had DISE findings consistent with circumferential palatal collapse; or had an AHI ≥ 50 events per hour. Patients were treated with upper airway stimulation (hypoglossal nerve stimulation). There was no comparator. Primary

outcomes were safety and the change in the apnea-hypopnea index (AHI) from baseline to 12 months postoperatively. Secondary outcomes consisted of QOL surveys. Among the 42 patients, there was a mean (SD) decrease in AHI of 12.9 (13.2) events per hour (95% CI, -17.0 to -8.7 events per hour). With the use of a therapy response definition of a 50% decrease in AHI, the 12-month response rate was 65.9% (27 of 41), and 73.2% of patients (30 of 41) had a 12-month AHI of less than 10 events per hour. The mean (SD) improvement in the OSA-18 total score was 34.8 (20.3) (95% CI, -42.1 to -27.5), and the mean (SD) improvement in the Epworth Sleepiness Scale score was 5.1 (6.9) (95% CI, -7.4 to -2.8). The mean (SD) duration of nightly therapy was 9.0 (1.8) hours, with 40 patients (95.2%) using the device at least 4 hours a night. The most common complication was temporary tongue or oral discomfort, which occurred in 5 patients (11.9%). The reoperation rate was 4.8% (n = 2). Study limitations consisted of: absence of control group; variation among 12-month polysomnograms (not all were full night at a single voltage level); and small sample size. The authors noted the study did not identify any significant prognostic factors and more study was needed in order to determine which children with DS are the best candidates for this procedure.

Stenerson et al. (2021) conducted a 44 month follow-up of four subjects that had participated in an earlier pilot study (Yu, et al.). Their objective was to assess the long-term need for implantable hypoglossal nerve stimulators and the necessity for voltage adjustment in children and young adults with Down syndrome. The four subjects, ages 10-13 years, were selected from the prior study as they underwent implantation at a young age and completed extended follow-up. All four participants underwent PSG between 44-58 months post-implantation during which time BMI was also calculated. Primary outcomes included stability of titration as measured by AHI, growth as measured by BMI and QOL as measured by the OSA-18 questionnaire. Compared to baseline, all 4 participants maintained reductions of at least 50% in AHI over the course of follow-up. Two participants had persistent, moderate OSA despite stimulation therapy. The other two participants achieved 100% reductions in AHI with stimulation therapy; when they underwent split-night sleep studies; the severe OSA persisted with the device turned off. Improvement in OSA-18 quality of life scores was observed in three of the four participants. The study was limited by a small sample size of 4 participants. While the apnea-hypopnea index (AHI) remains a diagnostic gold standard, it fails to capture the complete clinical profile of OSA. The authors noted additional long-term studies are needed to further evaluate device effectiveness and OSA progression through measures of gas exchange, neurocognitive outcomes, and quality of life. The further acknowledged that suitability of this device may differ in pediatric patients with DS who are less communicative or whose caregiver support is less involved. The concluded that while HNS continued to effectively control OSA in children with DS as they matured, their underlying untitrated OSA appears to persist into adulthood. The authors stated additional research is needed to better inform decisions on optimal age of implantation.

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA) considers upper airway stimulation via the hypoglossal nerve for the treatment of adult OSA syndrome to be a safe and effective second-line treatment of moderate to severe OSA in patients who are intolerant or unable to achieve benefit with PAP. This is not an evidence-based practice guideline rather the position statement is based on an informal process of expert or committee consensus (AAO-HNS, 2021). The AAO-HNS does not address the use of HNS in patients with Down Syndrome.

Although the benefits of HNS in individuals with Down syndrome and OSA have not been demonstrated in randomized controlled trials, growing evidence from case series has resulted in the adoption of this treatment as a reasonable option for this patient population.

Atrial Overdrive Pacing: Atrial overdrive pacing by means of an implantable cardiac pacemaker has been proposed as a treatment for central sleep apnea patients and in certain OSA patients

with some degree of heart failure. Atrial overdrive pacing consists of pacing at a rate higher than the mean nocturnal sinus rate. Investigators theorized that atrial overdrive pacing would improve vagal tone and increase upper airway muscle activity in patients with OSA.

Anastasopoulos et al. (2016) conducted a systematic review of 22 studies to evaluate the effect of different types of cardiac pacing on sleep-related breathing disorders in patients with or without heart failure. The included studies were classified according to the type of sleep disorder and the intervention undertaken. The authors reported that the evidence shows that cardiac resynchronization therapy, not atrial overdrive pacing, can reduce apneic events in central sleep apnea patients. Their effect on obstructive sleep apnea is controversial and pacing cannot be used alone as treatment of sleep-related breathing disorders. Further research is needed in order to elucidate the effect of these interventions in individual with sleep apnea.

Weng et al. (2009) conducted a meta-analysis of eight randomized controlled trials to determine the effects of atrial overdrive pacing on sleep apnea syndrome (n=129). Atrial overdrive pacing, as compared to non-pacing, reduced the apnea-hypopnea index (AHI) and increased the minimum arterial oxygen saturation (SaO₂) significantly in the central sleep apnea-predominant trials. No statistically significant increase in minimum SaO₂ was observed in the obstructive sleep apnea syndrome-predominant trials, however, and it was unclear whether AHI was reduced in these patients. The authors concluded that the role of atrial overdrive pacing in obstructive sleep apnea syndrome remains unclear.

Guidelines for device-based therapy published by the American College of Cardiology (ACC) and the American Heart Association (AHA) state that, a variety of heart rhythm disturbances may occur in OSA. Sinus bradycardia or pauses may occur during hypopneic episodes, and atrial tachyarrhythmias may also be observed, especially following an apnea episode. The guideline states that although a small retrospective trial demonstrated a decrease in central or OSA without reducing the total sleep time, subsequent randomized trials have not validated a role for atrial overdrive pacing in OSA (Epstein et al., 2013, 2008).

There is insufficient evidence to demonstrate the safety and efficacy of atrial overdrive pacing in the treatment of OSA.

Cautery-Assisted Palatal Stiffening Operation (CAPSO): CAPSO is an office-based procedure in which a midline strip of soft palate mucosa is removed, and the wound is left to heal by secondary intention. The procedure has been proposed as a treatment for OSA based on the premise that the resulting midline palatal scar stiffens the palate and eliminates palatal snoring. CAPSO has been performed with and without tonsillectomy and in conjunction with expansion pharyngoplasty.

In a systematic review and meta-analysis, Llewellyn et al. (2018) evaluated CAPSO with and without tonsillectomy and/or in conjunction with expansion pharyngoplasty. A total of eight studies (n=307) were evaluated including case series and prospective studies. The authors concluded that AHI improved by 41% for CAPSO alone, 61.7% for CAPSO with tonsillectomy and 52.1% for CAPSO with expansion pharyngoplasty. Lowest oxygen saturation, sleepiness and snoring improved after CAPSO.

Wassmuth et al. (2000) conducted a case series (n=25) to evaluate the ability of CAPSO to treat OSA. PSG was performed preoperatively and at three months following the procedure on all patients. Patients with a reduction in the AHI of 50% or more and an AHI of 10 or less were classified as responders. Based on these criteria, 40% of patients were considered to have responded to CAPSO. Mean AHI improved from 25.1 ± 12.9 to 16.6 ± 15.0 . The ESS improved

from 12.7 ± 5.6 to 8.8 ± 4.6 . The authors concluded that CAPSO is as effective as other palatal surgeries in the management of OSA.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of CAPSO in the treatment of OSA. Data from well-designed trials with adequate numbers of patients that compare this procedure with other treatments of OSA are lacking.

Injection Snoreplasty: Injection Snoreplasty is a treatment for snoring that involves the injection of a hardening agent into the upper palate. Sodium tetradecyl sulfate is the most common hardening agent used. Following the injection, scar tissue is reported to pull the uvula forward to eliminate palatal flutter associated with snoring. There is no evidence in the published medical literature to demonstrate the safety and efficacy of injection Snoreplasty in the treatment of OSA.

Pillar™ Palatal Implant System: The Pillar Palatal Implant System (Restore Medical, St. Paul, MN) received FDA 510(k) approval on December 18, 2002, for the treatment of snoring. On June 7, 2004, FDA approval of the Pillar System was expanded to include treatment of OSA. According to the FDA summary, the Pillar System consists of an implant and delivery tool, and is designed to stiffen the tissue of the soft palate to reduce the incidence of snoring in some patients and to reduce the incidence of airway obstruction in patients with mild to moderate OSA. The implant is a cylindrical-shaped segment of braided polyester filaments. The delivery tool consists of a handle and needle assembly that allows for positioning and placement of the implant in the submucosa of the soft palate.

A meta-analysis of the efficacy of the Pillar implant in the treatment of snoring and OSA was conducted by Choi et al. (2013). Efficacy for snoring (seven studies) and for mild to moderate OSA (seven studies) was analyzed separately. For patients with mild to moderate OSA, the Pillar implant significantly reduced the Epworth Sleepiness Scale ($p < .001$) and AHI ($p = .002$) compared to pre-procedure values. The authors noted that these results indicate that the Pillar implant has a moderate effect on snoring and mild to moderate OSA, but more studies with a high level of evidence are needed to arrive at a definite conclusion.

Friedman et al. (2007) conducted a retrospective review to assess subjective and objective improvement in 145 patients with mild to moderate OSA treated with a single-stage multilevel minimally invasive technique. All patients were treated with nasal surgery, palatal stiffening by Pillar implants, and radiofrequency volume reduction of the tongue base. Of 145 patients, 122 had a minimum follow-up of six months and complete data available for review. The primary outcome measure was change from baseline in AHI. The mean AHI decreased from 28.2 ± 7.6 preoperatively to 14.5 ± 10.2 postoperatively ($p < .0001$). Mean Epworth Sleepiness Scale (ESS) decreased from 9.7 ± 3.9 to 7.0 ± 3.3 ($p < .0001$). It is difficult to draw conclusions from this study due to its retrospective design, lack of long-term outcomes, and the inability to determine the individual impact of each procedure on short-term outcomes.

Nordgard et al. (2006) conducted a prospective nonrandomized study of 25 patients with untreated OSA with an AHI of 10–30, as determined by preoperative PSG, and BMI ≤ 30 . Three permanent implants were placed in the soft palate of each patient in an office setting under local anesthesia. A repeat PSG showed a mean decrease in AHI from 16.2 to 12.1 for the study group. Twenty of 25 patients demonstrated a reduced AHI, and 12 of 25 patients demonstrated an AHI of 10 or less 90 days post-implant. The mean ESS score decreased from 9.7 to 5.5. The authors concluded that palatal implants can significantly improve AHI and other sleep-related parameters in patients with mild to moderate OSA and BMI ≤ 30 , with short-term results comparable to those reported for UPPP. The authors acknowledged the lack of long-term outcomes in this study and

the limited number of patients. As with other palatal procedures, reduction in effectiveness over time may be expected. The authors further concluded that while short-term durability and effectiveness have been established, longer-term research needs to be conducted.

A multicenter non-comparative study was conducted by Walker et al. (2006) to evaluate the safety and effectiveness of the Pillar Palatal Implant System (n=53). Primary inclusion criteria were primary palatal contribution to OSA as determined by the investigator, an AHI of 10–30 events per hour, BMI ≤ 32 kg/m², age 18 or greater, and soft palate length adequate to accommodate a 28-mm implant. Each patient had three implants placed in the soft palate in an office procedure under local anesthesia. The primary outcome measure was AHI. PSG was performed prior to and 90 days following Pillar implantation. The AHI decreased from 25.0 ± 13.9 to 22.0 ± 14.8 events/hour ($p=0.05$). ESS scores, a secondary outcome measure, decreased from 11.0 ± 5.1 to 6.9 ± 4.5 ($p<0.001$). The AHI was reduced to below 10 in 12 patients (23%), and the AHI increased in 18 patients (34%). There were no serious complications. The most common adverse event was partial extrusion. Of 202 implants, 20 became partially exposed through the mucosa of the soft palate. All were removed and, in most cases, the implant was replaced.

AASM Practice Parameters for the Surgical Modification of the Upper Airway for OSA (Aurora, et al., 2010) discussed above, state that palatal implants may be effective in some patients with mild obstructive sleep apnea who cannot tolerate or are unwilling to adhere to PAP therapy, or in whom oral appliances have been considered and found ineffective or undesirable. Evidence is of very low quality, and while this procedure may be an alternate mode of therapy for mild OSA, it is difficult to predict if it will ultimately be found to be a reliably effective intervention.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of the Pillar System in the treatment of OSA.

Radiofrequency Volumetric Tissue Reduction (RFVTR): RFVTR (e.g., Coblation[®], Somnoplasty[®]) is a procedure used to remove redundant tissue in the upper airway. Although the procedure has been used to remove tissue from the turbinates and tonsils, recent studies of RFA in the treatment of OSA have limited the procedure to the soft palate, uvula and tongue base.

The ENTec[™] ReFlex[™] Wand (ArthroCare Corp., Sunnyvale, CA) received FDA approval through the 510(k) process on February 4, 2000, for ablation and coagulation of soft tissue in otolaryngological (ENT) surgery, including tissue in the uvula/soft palate for the treatment of snoring and submucosal palatal shrinkage. The ReFlex Wand is used to perform Coblation[®] treatment using radiofrequency energy. In 2002, the ENTec Plasma Wand received 510(k) approval for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in ENT surgery, including tissue of the uvula/soft palate for the treatment of snoring.

The Somnoplasty system (Somnus Medical Technologies, Sunnyvale, CA) received FDA 510(k) approval on July 17, 1997, for coagulation of soft tissue, including the uvula/soft palate. The 510(k) summary states that the Somnoplasty system may reduce the severity of snoring in some individuals. An expanded approval on November 2, 1998, states that the system is intended for the reduction of the incidence of airway obstruction in patients with upper airway resistance syndrome and OSA. The Somnoplasty system is comprised of an RF generator and tissue coagulating electrodes. The procedure is usually performed on an outpatient basis with local anesthesia.

AASM practice parameters discussed above (Aurora, et al., 2010) state that RFA can be considered in patients with mild to moderate OSA who cannot tolerate or are unwilling to adhere to PAP therapy, or in whom oral appliances have been considered and found ineffective or undesirable. This is noted to be a new recommendation based on very low quality evidence. The

average post-procedure AHI was found in 7 case series and one randomized controlled trial to be 14.9, consistent with residual mild OSA. The authors noted that RFA studies have shown improvement in subjective sleepiness and, in one study, quality of life. Because cardiovascular complications of OSA are associated with even lower values of AHI, patients treated with RFA should receive follow-up assessments for residual AHI, even if symptoms have improved. The authors also note that long-term sequelae of RFA are not published.

The systematic review by Franklin et al. (2009) to evaluate the efficacy and adverse effects of surgery for snoring and OSA, discussed above, concluded that there was no significant effect on daytime sleepiness and quality of life after radiofrequency ablation.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of RFVTR (e.g., Somnoplasty, Coblation) in the treatment of OSA.

Tongue-Base Suspension (e.g., The AIRvance™ System, ENCORE™ Tongue Suspension System): The Repose Bone Screw System (Influence, Inc., San Francisco, CA) received FDA 510(k) approval on August 27, 1999. The device name was changed to AIRvance in 2011 and is marketed by Medtronic. The system is used to perform anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded sutures. It is indicated for the treatment of OSA and/or snoring. The AIRvance System has been proposed as a sole treatment of OSA and has also been used in conjunction with UPPP and radiofrequency ablation.

A similar device to the AIRvance System is the ENCORE™ Tongue Suspension System (Siesta Medical, Inc., Los Gatos, CA). The ENCORE Tongue Suspension System received FDA 510(k) approval on July 1, 2011. The Encore System is intended for anterior advancement of the tongue base and hyoid suspension. It is indicated for the treatment of mild or moderate OSA and/or snoring. The AIRLIFT procedure utilizes the Encore™ System and the Revolution™ Suture Passer, an integrated set of instruments and implants specifically designed for hyoid and tongue suspension.

Bostanci and Turhan (2016) conducted a systematic review to evaluate existing research into the effectiveness and safety of two tongue base suspension (TBS) techniques (Repose® system and modified TBS) with or without uvulopalatopharyngoplasty (UPPP) in obstructive sleep apnea. Seven studies including 113 patients met the eligibility criteria for TBS as a stand-alone procedure. Four of seven studies including 62 patients used the Repose, and three studies including 51 patients used the modified TBS. The success rates were higher in the studies that used modified technique (74.5 %) than those that used the Repose (25.8%), ($p < 0.001$). Ten studies including 300 patients met the eligibility criteria for TBS combined with UPPP. Seven of ten studies including 176 patients used the Repose and three studies including 124 patients used the modified TBS. The success rates in this group were similar between the modified TBS (73.4%) and Repose (67.6%), ($p = 0.341$). When aggregate data of 413 patients were compared, the modified TBS was found to be associated with significantly higher success rates (73.7 vs. 56.7%, $p < 0.001$). The evidence supports primarily grade C recommendations for the benefits of both techniques with and without UPPP. There is a trend toward improved outcome with the modified technique.

Kuhnel et al. (2005) conducted a prospective nonrandomized study ($n = 28$) to demonstrate the efficacy of tongue base suspension with the Repose System in the treatment of OSA. PSG was performed before as well as three and 12 months after surgery. Lateral cephalometric radiography and video endoscopy of the pharynx were performed preoperatively and postoperatively to identify morphological changes in the posterior airway space. A suspension suture anchored intraorally at the mandible was passed submucosally in the body of the tongue, with suture

tightness adjusted individually. The posterior airway space was widened by at least 2 mm in 60% of cases. Daytime sleepiness improved subjectively in 67% of patients, and the RDI improved postoperatively in 55% of patients. The correlation between posterior airway space widening and the improvements in daytime sleepiness and respiratory disturbance index was not significant. The authors concluded that surgical intervention in obstructive sleep apnea syndrome with the Repose System does not result in permanent anatomical change in the posterior airway space.

Miller et al. (2002) conducted a retrospective analysis of the Repose System for the treatment of OSA to describe preliminary experience using the system in conjunction with UPPP in the multilevel surgical approach. The authors evaluated 19 consecutive patients undergoing UPPP and the Repose System tongue base suspension for the management of OSA during a one-year period (1998 through 1999). Fifteen patients had complete preoperative and postoperative PSG data. A 46% reduction in RDI was demonstrated at a mean of 3.8 months after surgery. The apnea index demonstrated a 39% reduction. The authors concluded that the Repose System in conjunction with UPPP has been shown to produce significant reductions in the RDI and apnea index, as well as a significant increase in oxygen saturation. Despite the improvement in these objective parameters, the overall surgical cure rate was only 20% (three of 15 patients) in this retrospective series. Further research is warranted to define the role of the Repose System in the management of obstructive sleep apnea patients.

There is insufficient evidence in the published medical literature to support the safety, efficacy, and long-term outcomes of the use of tongue-base suspension in the treatment of OSA.

Tongue Implant (e.g., The ReVent System): The ReVent System (ReVent® Medical, Inc., Alamo, CA) has CE mark approval and is available on a limited basis in Europe. The device is not FDA-approved. The system is intended for use in stabilizing the tongue for the reduction of the incidence of tongue based airway obstruction in patients with OSA. The implants are inserted using a minimally invasive technique providing a light spring-like force to the tissue. After the implants heal into place with the looped ends acting as an anchoring mechanism, the bio-absorbable sections between the looped ends of the implants erode allowing the implants to contract over time. The spring-like force is designed to maintain an open airway (Pavelec, et al., 2016)

There is insufficient evidence in the published medical literature to support the safety, efficacy, and long-term outcomes of the use of the ReVent System in the treatment of OSA.

Transpalatal Advancement Pharyngoplasty: Volner et al. (2017) conducted a systematic review and meta-analysis to evaluate if apnea-hypopnea index (AHI) and lowest oxygen saturation (LSAT) improve after transpalatal advancement pharyngoplasty (TPAP) with OSA in adults. All studies that included patients who underwent TPAP alone were included in the analysis. Five studies met criteria (n=199). Although improvements were seen in both AHI and LSAT after TPAP, the authors recommend additional studies, especially prospective studies. Research comparing TPAP procedures with palatal advancement are needed to determine the optimal role for this procedure.

Evidence evaluating this technique is limited, consisting primarily of retrospective reviews. There is insufficient evidence in the published medical literature to determine the safety and efficacy of this procedure or to determine how it compares to available treatment options for OSA.

Professional Societies

American Academy of Sleep Medicine (AASM): Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine clinical practice guideline (Kent, et al., 2021), based on a systematic review of the literature and an assessment of the evidence

using the GRADE process, is an update to the practice parameters published in 2010. The previous practice parameters addressed specific surgical procedures, but did not address when the appropriate time is to consider surgical treatment.

Recommendations are assigned a strength of "STRONG" if considered a recommendation clinicians should follow under most circumstances, or "CONDITIONAL" if clinicians should use clinical knowledge, experience, patient values and patient preferences to determine the best course of action. The recommendations include:

1. We recommend that clinicians discuss referral to a sleep surgeon with adults with OSA and BMI<40 who are intolerant or unaccepting of PAP as part of a patient-oriented discussion of alternative treatment options. (STRONG)
2. We recommend that clinicians discuss referral to a bariatric surgeon with adults with OSA and obesity (class II/III, BMI ≥35) who are intolerant or unaccepting of PAP as part of a patient-oriented discussion of alternative treatment options. (STRONG)
3. We suggest that clinicians discuss referral to a sleep surgeon with adults with OSA, BMI<40, and persistent inadequate PAP adherence due to pressure-related side effects as part of a patient-oriented discussion of adjunctive or alternative treatment options. (CONDITIONAL)
4. We suggest clinicians recommend PAP as initial therapy for adults with OSA and a major upper airway anatomic abnormality prior to consideration of referral for upper airway surgery. (CONDITIONAL)

Practice Parameters for the Surgical Modification of the Upper Airway for Obstructive Sleep Apnea in Adults (Aurora, et al., 2010), based on a systematic review of the literature (Caples, et al., 2010), updated earlier practice parameters published in 1996.

Recommendations are classified as Standard, Guideline, or Option, in descending order based on the benefits vs. harms and the quality of evidence. Recommendations for individual procedures are included in the relevant sections below.

Standard:

- The presence and severity of obstructive sleep apnea (OSA) must be determined before initiating surgical therapy
- The patient should be advised about potential surgical success rates and complications, the availability of alternative treatment options such as nasal positive airway pressure and oral appliances, and the levels of effectiveness and success rates of these alternative treatments.
- The desired outcomes of treatment include resolution of the clinical signs and symptoms of OSA and the normalization of sleep quality, the apnea-hypopnea index, and oxyhemoglobin saturation levels.

Option

- Maxillo-mandibular advancement (MMA) is indicated for surgical treatment of severe OSA in patients who cannot tolerate or who are unwilling to adhere to positive airway pressure therapy, or in whom oral appliances, which are more often appropriate in mild and moderate OSA patients, have been considered and found ineffective or undesirable.
- Uvulopalatopharyngoplasty (UPPP) as a sole procedure, with or without tonsillectomy, does not reliably normalize the apnea hypopnea index (AHI) when treating moderate to severe OSA syndrome. Therefore, patients with severe OSA should initially be offered positive airway pressure (PAP) therapy, while those with moderate OSA should initially be offered either PAP therapy or oral appliances.

- Use of multi-level or stepwise surgery (MLS), as a combined procedure or as stepwise multiple operations, is acceptable in patients with narrowing of multiple sites in the upper airway, particularly if they have failed UPPP as a sole treatment.
- Laser-assisted uvulopalatoplasty (LAUP) is not routinely recommended as a treatment for obstructive sleep apnea syndrome.
- Radiofrequency ablation (RFA) can be considered as a treatment in patients with mild to moderate OSA who cannot tolerate or who are unwilling to adhere to PAP therapy, or in whom oral appliances have been considered and found ineffective or undesirable.
- Palatal implants may be effective in some patients with mild OSA who cannot tolerate or who are unwilling to adhere to PAP therapy, or in whom oral appliances have been considered and found ineffective or undesirable.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): No evidence-based practice guidelines were found by the AAO-HNS that address the treatment of OSA. The AAO-HNS has published several position statements related to OSA treatment options; however, these documents are based on an informal process of expert or committee consensus (AAO-HNS website).

American Academy of Pediatrics (AAP): The 2012 AAP Clinical Practice Guideline, Diagnosis and Management of Childhood Obstructive sleep Apnea Syndrome key action statement for adenotonsillectomy states that if a child is determined to have OSA, has a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery, the clinician should recommend adenotonsillectomy as the first line of treatment. If the child has OSA but does not have adenotonsillar hypertrophy, other treatment should be considered. Clinical judgment is required to determine the benefits of adenotonsillectomy compared with other treatments in obese children with varying degrees of adenotonsillar hypertrophy. (Evidence Quality: Grade B, Recommendation Strength: Recommendation) (Marcus, et al., 2012).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No Determination found	
LCD	CGS Administrators, LLC	Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38307)	3/7/2024
LCD	National Government Services, Inc.	Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea (L38387)	4/1/2020
LCD	Palmetto GBA	Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea (L38276)	4/13/2023

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Considered medically necessary when criteria in the applicable policy statements listed above are met for the treatment of sleep apnea. Considered not medically necessary for the treatment of snoring in the absence of sleep apnea.

CPT®* Codes	Description
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
21198	Osteotomy mandible segmental
21199	Osteotomy, mandible, segmental; with genioglossus advancement
21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)
21685	Hyoid myotomy and suspension
42145	Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64568	Open implantation cranial nerve (eg, 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
64585	Revision or removal of peripheral neurostimulator electrode array

HCPCS Codes	Description
C1767	Generator, neurostimulator (implantable), non rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8688	Implantable neurostimulator pulse generator, dual array, non rechargeable, includes extension

Considered Experimental/Investigational/Unproven when used to report uvulectomy as a stand-alone procedure for the treatment of obstructive sleep apnea:

CPT®* Codes	Description
42140	Uvulectomy, excision of the uvula

Additional Procedures/Services

Considered Experimental/Investigational/Unproven for the treatment of sleep apnea:

CPT®* Codes	Description
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial
41512	Tongue base suspension, permanent suture technique
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
42160	Destruction of lesion, palate or uvula (thermal, cryo or chemical)
42950	Pharyngoplasty (plastic or reconstructive operation on pharynx)

HCPSC Codes	Description
C9727	Insertion of implants into the soft palate; minimum of three implants

Considered Experimental/Investigational/Unproven when used to report cautery-assisted palatal stiffening operation (CAPSO), injection Snoreplasty, or transpalatal advancement pharyngoplasty:

CPT®* Codes	Description
42299	Unlisted procedure, palate, uvula

Considered Experimental/Investigational/Unproven when used to report tongue implant (e.g., ReVent System):

CPT®* Codes	Description
41599	Unlisted procedure, tongue, floor of mouth

***Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	<ul style="list-style-type: none">•Added policy statements to address use of hypoglossal airway stimulation in adolescents with obstructive sleep apnea and Down syndrome•Updated coverage statement addressing use of hypoglossal airway stimulation in adults, based on current FDA language•Added statements to address use of Drug-Induced Sleep Endoscopy in children•Clarified statement addressing uvulectomy•Removed statements and codes addressing tracheostomy, tonsillectomy and adenoidectomy	12/15/2024
Annual review	<ul style="list-style-type: none">•Updated to new template and formatting standards.•Removed policy statements pertaining to replacement of generator battery and/or leads and laser-assisted uvulopalatoplasty (LAUP).	10/15/2023

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