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 (OSA) 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 OSA when criteria for positive airway pressure (PAP) met and documentation that demonstrates PAP treatment failure, defined as an inability to eliminate OSA (apnea-hypopnea index [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)
- 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 not medically necessary.

Uvulectomy performed for other indications, e.g., airway obstruction, acute inflammation/angioedema of the uvula, globus sensation, coughing, choking, or gagging symptoms due to elongated uvula is not addressed in this Coverage Policy.

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, an 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, an 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 adult when ALL of the following criteria are met:

- Device-specific indications for age and AHI on polysomnography (PSG)

Device	Age	AHI on PSG
Inspire II Upper Airway Stimulator (Inspire Medical Systems)	≥ 18 years	≥ 15 and ≤100 events per hour
Genio® System 2.1 (Nyxoah S.A.)	≥ 22 years	≥ 15 and ≤65 events per hour

- central + mixed apneas ≤ 25% of total AHI
- 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 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

An FDA-approved implantable upper airway hypoglossal nerve stimulation device is considered medically necessary for the treatment OSA in a pediatric individual with Down syndrome when ALL of the following criteria are met:

- Device-specific indications for age and AHI on PSG

Device	Age	AHI on PSG
Inspire II Upper Airway Stimulator (Inspire Medical Systems)	13-18 years	>10 and < 50 events per hour

- 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 home sleep apnea testing (HSAT) and PSG testing pre- and post-upper airway hypoglossal nerve stimulator implantation are covered in the Sleep Disordered Breathing 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)
- transpalatal advancement pharyngoplasty (TPAP)

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

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 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
64568	Open implantation of 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

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
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non rechargeable, includes extension

Considered Not Medically Necessary 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
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)

HCPCS 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

General Background

Obstructive sleep apnea (OSA) is characterized by recurrent episodes of complete or partial upper airway obstruction during sleep. This obstruction may result in apneas, hypopneas, respiratory effort-related arousals, disrupted sleep, and gas exchange abnormalities. Early identification and treatment of OSA are important to help reduce associated morbidity (Kline, 2025; Paruthi, 2025).

The gold-standard diagnostic test for OSA is attended, in-laboratory polysomnography (PSG), sometimes referred to as a sleep study. PSG is a noninvasive procedure that identifies obstructive events and quantifies the severity of OSA. Drug-Induced Sleep Endoscopy (DISE) is non-routine, minimally invasive diagnostic test for OSA that uses a flexible fiberoptic endoscope to assess the upper airway (Kline, 2025; Paruthi, 2025).

In children, the decision to initiate treatment for OSA and the choice of treatment is based on factors including age, clinical symptoms, comorbidities, risk factors, and diagnostic test results. Adenotonsillectomy, watchful waiting for up to six months, or positive airway pressure (PAP) therapy may be appropriate. Treatments proposed for OSA in select cases may include rapid maxillary expansion, mandibular advancement device, corticosteroids, anti-inflammatory therapy, other adjunctive therapies, and adjuvant surgical procedures. Hypoglossal nerve stimulation may also be appropriate for select pediatric individuals with OSA and Down syndrome (Paruthi, 2025).

In adults, the first-line treatments for OSA include behavior modification and PAP therapy. Behavior modification includes weight loss, diet, and exercise for obesity, altering sleep position with positional OSA, and avoidance of alcohol and medications that exacerbate OSA. Oral appliances may also be appropriate. Surgical treatments, including hypoglossal nerve stimulation, may be appropriate for select adults unresponsive, unable to tolerate, or who decline PAP therapy (Malhotra and Kundel, 2025).

Professional Societies/Organizations

American Academy of Sleep Medicine (AASM): An AASM clinical practice guideline for the referral of adults with OSA for surgical consultation (Kent et al., 2021a) replaced the previously published guideline on the use of surgery to treat adults with OSA (Aurora, 2010). AASM notes that the new guideline does not provide recommendations for individual surgical procedures. The guideline focuses on the body of evidence from a systematic review and meta-analysis (Kent et al., 2021b) regarding the referral of adults with OSA for surgical consultation.

- "Recommendation 1: We recommend that clinicians discuss referral to a sleep surgeon with adults with OSA and BMI < 40 kg/m2 who are intolerant or unaccepting of PAP as part of a patient-oriented discussion of alternative treatment options (STRONG)."
- "Recommendation 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)."
- "Recommendation 3: We suggest 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 part of a patient-oriented discussion of adjunctive or alternative treatment options (CONDITIONAL)."
- "Recommendation 4: We suggest that 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)."

Drug-Induced Sleep Endoscopy (DISE)

Drug-induced sleep endoscopy (DISE) is a diagnostic procedure for OSA that is used to assess the upper airway. The procedure is performed during anesthetically-simulated sleep that preserves spontaneous respiration. Using a flexible fiberoptic endoscope, DISE may enable direct visualization of dynamic upper airway behavior, including sites of collapse, obstruction, and changes in airway lumen (Kirkham, 2025; Schwab, 2025). DISE may help direct OSA surgical treatment and predict outcomes in select adults, adolescents with Down syndrome, and children (Berry, et al., 2025; Katz, 2025).

Literature Review

According to the published clinical evidence, DISE may be considered to help guide the surgical treatments of OSA in select patients.

Qi et al. (2024) conducted a systematic review and meta-analysis to analyze the failure rate of single-level and multi-level upper airway surgeries for OSA guided by DISE. The authors also aimed to identify risk factors for surgical failure to provide evidence for the surgical treatment of individuals with OSA. The systematic review included 25 studies reporting on 1522 individuals. Single-level surgery was performed in 14 studies and multi-level surgery was performed in 11 studies. Inclusion criteria included case series, cohort studies, and RCTs of upper airway surgery for OSA, where DISE was used to evaluate the site of obstruction, and surgical failure rates and outcomes were statistically analyzed. Review articles, letters, case reports, commentary, and

pediatric studies were excluded. Studies were also excluded if the velum, oropharynx, tongue base, and epiglottis (VOTE) scoring system was not used to assess the obstruction site and the Sher criteria was not used to calculate the surgical failure rate. The duration of follow-up among the included studies ranged from 2 to 12 months. The study results revealed that the overall median failure rate was 37% (95% confidence interval [CI] 0.31 to 0.44; I^2 = 85.97%, p<0.001). The median failure rate for single-level and multi-level surgery was 35% (95% CI 0.25 to 0.44; I^2 = 85.94%, p<0.001) and 41% (95% CI 0.33 to 0.48; I^2 = 77.83%, p<0.001), respectively. The failure rate for single-level surgery was significantly lower compared to multi-level surgery (p<0.001). The baseline apnea-hypopnea index (AHI) (p=0.001) and body mass index (BMI) (p<0.001) for individuals undergoing multi-level surgery were significantly higher than those undergoing single-level surgery. Major risk factors for surgical failure included circumferential velum collapse at the velum, oropharyngeal lateral wall collapse, small tonsils at the oropharynx, anterior-posterior lingual collapse, and complete collapse at the tongue base. Higher BMI and larger preoperative AHI were also associated with failure. The authors concluded that upper airway surgery for OSA guided by DISE had a low failure rate of 37%. DISE can identify obstruction sites associated with surgical failure and guide single-level and multi-level surgeries. However, larger-scale and long-term follow-up studies to improve the accuracy and reliability the study conclusions were recommended. Limitations of the systematic review include the quality of available studies, inclusion criteria and DISE procedure heterogeneity, differing follow-up intervals, and lack of a non-DISE comparator.

Saniasiaya and Kulasegarah (2020) conducted a systematic review to determine the outcome of DISE directed surgery in children with OSA. Seven articles (n=996), including retrospective, case-control, and prospective studies, were included. Following DISE, 295 children (30%) had changes in their surgical decision and 86% underwent multi-level 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 for individuals with OSA. Nine studies (n=1247; 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 individuals 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.

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): A position statement from the AAO-HNS (2021) regarding the treatment of OSA states:

- "Drug induced sleep endoscopy (DISE) is useful to determine the best management strategy in children with persistent OSA." (Pediatric OSA)
- "DISE may be useful in determining the most effective OSA surgical treatment plan." (Adult OSA)

Uvulopalatopharyngoplasty (UPPP)

Uvulopalatopharyngoplasty (UPPP) and UPPP variants are the most commonly performed surgical procedures for OSA. UPPP involves reducing, tightening, and/or repositioning the soft palate and related oropharyngeal structures. UPPP often includes the reduction, removal, or reconfiguration of the uvula. A palatine tonsillectomy may also be performed simultaneously when tonsils are present. UPPP variants include uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, and relocation pharyngoplasty. Some variants may be combined to address complicated palatal obstruction. UPPP may involve excision

of palatal tissue, but newer approaches include less resection and more reconstructive approaches. Selection of the optimal UPPP variant depends on individual anatomy and functional examination of the upper pharynx and palate (Weaver and Kapur, 2024).

Literature Review

The published clinical evidence suggests UPPP may be considered for select patients but should be approached with caution due to variable efficacy and documented risks.

Najafi et al. (2024) conducted a prospective cohort study to determine whether continuous positive airway pressure (CPAP) and UPPP improved the quality of life (QOL) for 88 participants with OSA. Inclusion criteria included age at least 13 years old, moderate OSA (AHI or respiratory disturbance index [RDI] between 15 and 30), and CPAP non-adherence (<4 hours/night). Participants were divided into three groups based on treatment preference: CPAP group (n=40), UPPP group (n=38), and control group (no treatment) (n=10). (Participants in the UPPP group demonstrated velum obstruction based on DISE.) Change in QOL was compared between the CPAP group and UPPP group using the Sleep Apnea Quality of Life Index (SAQLI) questionnaire before and at six months after treatment. Correlation of post-treatment SAQLI scores with (BMI), RDI, and age were also assessed. The study results revealed that both CPAP and UPPP significantly improved QOL compared to the control ($p<0.001$). The initial comparison between CPAP and UPPP showed no statistically significant difference in post-treatment QOL ($p=0.091$). However, after removing outliers, UPPP was significantly superior to CPAP ($p=0.042$). Weak correlations were observed between post-treatment SAQLI and BMI ($r=0.037$), RDI ($r =0.096$), and age ($r=0.022$). The authors concluded CPAP and UPPP improved QOL. UPPP could be considered an effective treatment for this study population. Limitations of the study include small sample size, non-randomized design, study population consisting of only individuals with moderate OSA, lack of comparison to other methods of OSA management, and unassessed safety and efficacy outcomes.

Franklin et al. (2009) conducted a systematic review to evaluate the efficacy and adverse effects of surgery for snoring and OSA. The systematic review included four randomized controlled trials (RCTs) of surgery versus either sham surgery or conservative treatment in adults. The trials included outcome measures of daytime sleepiness, QOL, AHI, and snoring. There was no significant effect on daytime sleepiness and QOL after laser-assisted uvulopalatoplasty (LAUP). 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 UPPP and uvulopalatoplasty, 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 is required to determine whether surgery is curative or whether the signs and symptoms of OSA tend to recur, requiring further treatment.

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): A position statement from the AAO-HNS (2021) regarding the treatment of OSA states:

- "Surgical management may also be indicated for adult patients with OSA when PAP therapy is inadequate, such as when the patient is intolerant of CPAP or CPAP therapy is unable to eliminate OSA."

- "For example, UPPP and tonsillectomy has been shown to be effective in improving OSA in approximately 80% of patients with favorable anatomy."

A position statement from the AAO-HNS (2019) regarding UPPP states:

- "Uvulopalatopharyngoplasty (UPPP) is a valid and generally safe treatment for OSAS in appropriately selected patients (Kezirian 2004)."
- "UPPP and its modifications have also been shown to be effective in the pediatric population, especially in handicapped populations with poor palatal control and redundant soft tissue."
- "UPPP and its modifications are important treatments for OSA in patients who have demonstrated an inability to consistently use continuous positive airway pressure (CPAP) therapy or other medical treatments."
- "Uvulopalatopharyngoplasty and its variants are safe, effective therapies that result in important health and quality of life improvements in properly selected patients."

Uvulectomy

Uvulectomy, the surgical removal of the uvula, has been proposed as a stand-alone procedure to improve airflow in individuals with OSA. However, reduction, removal, or reconfiguration of the uvula is more often performed as part of UPPP, a more comprehensive and efficacious approach to treat OSA (Weaver & Kapur, 2024).

Literature Review

There are no well-designed studies in the peer-reviewed medical literature that evaluate uvulectomy for the treatment of OSA. 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.

Uvulectomy performed for other indications, e.g., airway obstruction, acute inflammation/angioedema of the uvula, airway obstruction, globus sensation, coughing, choking, or gagging symptoms due to elongated uvula are not addressed in this Coverage Policy.

Multi-Level or Stepwise surgery (MLS)

Surgical treatment for select patients with OSA may involve either multiple staged procedures or single-stage combined approaches. Approximately one-third or more of patients present with lower pharyngeal and/or laryngeal obstruction, either in isolation or in combination with upper pharyngeal obstruction. This anatomical complexity often necessitates multi-level surgical intervention to adequately address airway collapse and improve outcomes (Weaver & Kapur, 2024)

Literature Review

Successful polysomnographic outcomes following multiple staged procedures or single-stage combined approaches are reported in the literature (Caples, et al., 2010; Lin et al., 2008; Kezirian, et al., 2006;). However, high-level clinical evidence remains limited, as most studies are observational or lack rigorous controls.

Maxillomandibular Advancement (MMA)

Maxillomandibular advancement (MMA) is a surgical procedure used to treat OSA by repositioning the upper and lower jaw bones forward. This advancement increases the size and stability of the upper airway and places surrounding soft tissues under tension, improving airflow during sleep. The procedure often requires pre- and postoperative orthodontic treatment to correct dental occlusion. MMA is typically reserved for patients with persistent, severe OSA who have not responded to other surgical interventions or who present with maxillary or mandibular hypoplasia (Weaver and Kapur, 2024).

Literature Review

MMA is considered a safe and effective treatment for OSA in select individuals, particularly those with craniofacial abnormalities or persistent OSA following other interventions, according to the published clinical evidence.

Walker et al. (2025) conducted a systematic review and meta-analysis to provide an updated evaluation of clinical effectiveness and sequelae of MMA for OSA. The systematic review included 31 studies reporting on 1597 individuals. Inclusion criteria included studies of individuals who underwent MMA for OSA, age 18 years or above, and that reported adverse events. Non-English articles and studies of syndromic individuals, cleft lip/cleft palate, or single jaw surgeries were excluded. The primary objective of the systematic review was to evaluate MMA risks, types, rates, and related factors related, as well as provide an update on clinical effectiveness in this population. The study results revealed that MMA resulted in improvements in AHI, respiratory disturbance index (RDI), blood oxygen saturation nadir, Epworth sleepiness scale (ESS), and BMI by -41.87/hour (-49.86 to -33.89), -46.24/hour (-62.18 to -30.29), 6.29% (3.42 to 12.08), -8.69 (-11.54 to -5.83), and -0.74 kg/m^2 [-1.35 to -0.12], respectively. Early lower facial numbness (83.40%), late lower facial numbness at less and greater than 1 year follow-up (66.51% and 32.73% respectively), and hardware removal (21.99%) were noted as the sequelae with the greatest incidence. Persistent OSA was 16.27%. A positive correlation between both preoperative BMI and length of hospital stay ($r=0.81$, $p=0.052$) and age and lower facial numbness ($r=0.42$, $p=0.196$) was noted. A negative correlation between change in AHI and time to follow up ($r=0.75$, $p=0.087$) was also noted. Limitations of the systematic review include possible inclusion of crossover data, lack of follow up time in which late lower facial numbness was experienced, and sole inclusion of studies that included adverse events, which may lead to overestimation. Additionally, the systematic review included only one RCT. The majority of the included studies were retrospective cohort/observational, followed by prospective cohort, and case series.

Al-Bayyati et al. (2025) conducted a systematic review and meta-analysis to assess the effect of MMA on patient-reported outcome measures (PROMs) focusing on health-related quality of life (HRQOL) for individuals with OSA. The systematic review included 12 studies reporting on 317 individuals. Inclusion criteria included studies of individuals who underwent MMA for OSA, age 18 years or above, published in English, and reported PROMs related to HRQOL. Case reports, review articles, and articles with no full text available were excluded. The primary objective was to determine the main changes in HRQOL. The study results revealed that MMA was associated with a 5.35-point improvement in ESS (95% CI -6.57 to -4.14; $Z=-8.62$; $p<0.001$) and a 3.96-point improvement in Functional Outcomes of Sleep Questionnaire scores (95% CI 3.11 to 4.80; $Z=11.60$; $p<0.001$). An improvement in all domains of the Short Form 36 Health Survey was also reported. The authors concluded that MMA was well received by individuals with OSA and resulted in clinically meaningful improvements in PROMs related to HRQOL. However, further standardized research for an adequate analysis is necessary. Limitations of the systematic review include use of observational cohort studies and lack of RCTs. Assessing PROMs introduces outcome reporting bias. Some characteristics of interest, including age, gender, and ethnicity, as well as mean follow-up duration were not reviewed. There was inconsistent and heterogeneous reporting of

HRQOL measures. Of note, the systematic review did not report on adverse events and treatment complications.

Holty and Guilleminault (2010) conducted a systematic review and meta-analysis of 22 studies (n=627 individuals) to evaluate the clinical efficacy and safety of MMA 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 QOL 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. However, additional long-term cohort studies are needed to better evaluate MMA clinical outcomes and to identify the population with OSA most likely to benefit.

Implanted Upper Airway Hypoglossal Nerve Stimulation Devices

Implanted upper airway hypoglossal nerve stimulation devices are increasingly used for the treatment of OSA in select patients. The device is implanted during a minimally invasive surgical procedure. During sleep, the device monitors respirations to synchronize neurostimulation of the hypoglossal nerve with the initiation of inspiration. Stimulation of the hypoglossal nerve moves the tongue forward and may help open the airway. An external remote is used to control the device (Suurna, 2025).

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 hypoglossal nerve stimulation has therefore been explored as a treatment option for individuals with Down syndrome.

U.S. Food and Drug Administration (FDA)

Devices for implantable upper airway hypoglossal nerve stimulation include the Inspire II Upper Airway Stimulator (Inspire Medical Systems) and the Genio® System 2.1 (Nyxoah S.A.).

On April 30, 2014, the Inspire II Upper Airway Stimulator received FDA Premarket Approval (PMA) (P130008). Several PMA supplements are noted for the Inspire II Upper Airway Stimulator. On June 8, 2023, a supplement to the original Inspire II Upper Airway Stimulator received PMA (P130008/S090). The Approval Order Statement indicates, "Approval to expand the indications for use to OSA patients with an upper limit baseline apnea-hypopnea index (AHI) to 100 (increase from <= 65 to <=100) and increasing the an [sic] upper limit body mass index (BMI) warning to 40 (increase from <=32 to <=40)." The Approval Order states: "Inspire® Upper Airway Stimulation (UAS) is used to treat a subset of patients with moderate to severe obstructive sleep apnea (OSA) (apnea-hypopnea index [AHI] of greater than or equal to 15 and less than or equal to 100). Inspire UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level.

PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

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

Inspire UAS is also indicated for use in patients between the ages of 18 to 21 with moderate to severe OSA (15≤AHI≤100), and pediatric patients ages 13 to 18 years with Down syndrome and AHI greater than 10 and less than 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."

On August 8, 2025, the Genio System 2.1 (Nyxoah S.A.) received FDA PMA (P240024). The FDA Approval Order states: "This device is indicated for use in the treatment of moderate to severe Obstructive Sleep Apnea (OSA) (apnea-hypopnea index [AHI] of greater than or equal to 15 and less than or equal to 65). The Genio® System 2.1 is intended for adult patients 22 years of age and older who have been confirmed to fail, cannot tolerate or are ineligible to be treated with current standard of care treatments including lifestyle modifications, positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BiPAP] machines), oral appliances (such as mandibular advancement devices), and pharmacotherapy (such as tirzepatide).

PAP failure is defined as an inability to eliminate OSA (residual AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

1. Inability to use PAP (at least 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or
2. Unwillingness to use PAP (PAP therapy initiated and subsequently discontinued by choice)."

Additionally, the FDA-approved The Genio® System 2.1 (Implantable Stimulator Model #2954) – Surgeon Manual (P240024) notes: "Safety and effectiveness in the following groups have not been established with the Genio® System 2.1:

- Patients younger than 22 or older than 75 years of age
- Patients with a Body Mass Index (BMI) greater than 32 kg/m2
- Patients with an Apnea Hypopnea Index (AHI) less than 15 or greater than 65 events/hr
- Patients with Complete Concentric Collapse (CCC) at the soft palate level"

Device or Product	Identifier	Manufacturer	Decision Date
Inspire II Upper Airway Stimulator	P130008	Inspire Medical Systems	4/30/2014
Genio System 2.1	P240024	Nyxoah S.A.	8/25/25

*FDA product code: MNQ

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review (adult)

Published evidence evaluating implanted upper airway hypoglossal nerve stimulation devices for the treatment of OSA consists primarily of prospective and retrospective case series and registry data. Implanted upper airway hypoglossal nerve stimulation devices have not been evaluated in well-designed RCTs. Although the evidence is not robust, there is adequate evidence to support the safety and efficacy of implanted upper airway hypoglossal nerve stimulation devices for the treatment of moderate to severe OSA in carefully selected patients who are intolerant of or unwilling to use PAP.

Kim et al. (2024) conducted a systematic review and meta-analysis to assess the relative effectiveness of hypoglossal nerve stimulation and alternative surgical interventions for managing OSA. The systematic review included 10 studies, two RCTs and eight cohort studies, involving 2209 individuals. Eligible studies included those that reported polysomnographic outcomes and sleep apnea-related QOL, before and after hypoglossal nerve stimulation, with comparisons made to control groups, CPAP, or surgical procedures such as UPPP, expansion sphincter pharyngoplasty, or tongue base surgery. The primary outcome measures were the AHI, oxygen desaturation index (ODI), and ESS. Secondary outcome measures included the percentages of AHI < 5, < 10, and < 15 events/hour, and success rate based on the Sher criteria after hypoglossal nerve stimulation. Success based on the Sher criteria was defined as a drop in postoperative AHI by 50% or to a value < 20 events/hour. The study results revealed that compared to other airway surgeries, the rates of post-treatment AHI < 10 and < 15 events/hour were lower in the hypoglossal nerve stimulation group (odds ratio [OR] 5.33, 95% CI 1.21 to 23.42; and 2.73, 95% CI 1.30 to 5.71, respectively). Postoperative AHI was also lower in the hypoglossal nerve stimulation group than in all other airway surgery groups (AHI: mean difference [MD] -8.00, 95% CI -12.03 to -3.97 events/hour). However, there were no differences determined to be significant in the rate of post-treatment AHI < 5 events/hour (OR 1.93, 95% CI 0.74 to 5.06) or postoperative ESS score (MD 0.40, 95% CI 1.52 to 2.32) between the two groups. The authors concluded that hypoglossal nerve stimulation could be an effective alternative option for CPAP intolerant individuals with moderate-to-severe OSA. Limitations of the systematic review include the few numbers of available RCTs, heterogeneity between studies, and lack of adverse events analysis. Half of the of the included studies were retrospective. Additional RCTs using comparable treatment protocols would be helpful to confirm these results.

Wollny et al. (2024) conducted a systematic review and meta-analysis of clinical trials and real-world data to evaluate adverse events and complications associated with hypoglossal nerve stimulation therapy for the treatment of OSA. The systematic review included 17 studies involving 1962 individuals. Inclusion criteria included publication in English language, follow-up period of at least 6 months after implantation, follow-up data of at least 10 individuals, and reporting on all-cause mortality, explantation or replacement, re-operation or revision, bleeding or hematoma, postoperative pain, tongue abrasion, neuropraxia, and discomfort related to stimulation. Review articles, case reports, editorials, abstracts, publications involving pediatric populations, and non-English language articles were excluded. The primary outcomes of interest included the documented rates of adverse events and complications associated with hypoglossal nerve stimulation therapy. The study results revealed a pooled mortality rate of 0.01% (95% CI = 0.0 to 0.2%) (average follow-up duration of 17.5 ± 16.9 months). All reported deaths were determined to be unrelated to hypoglossal nerve stimulation therapy. Hypoglossal nerve stimulation system survival probability was 0.9834 (95% CI = 0.9768 to 0.9882) (60-month follow-up). Infections and request for removal were the most common indications. The pooled surgical revision rate was 0.08% (95% CI 0.0 to 0.2%). Transient stimulation-related discomfort (0.08%, 95% CI = 0.0 to 0.2%) and tongue abrasions (0.07%, 95% CI = 0.0 to 0.2%) were the most reported treatment-related side effects. The authors concluded that hypoglossal nerve stimulation therapy for the treatment of OSA was associated with a positive patient safety profile. Adverse events occurred

primarily at device implantation and during the treatment acclimatization period. Limitations of the systemic review include lack of available RCTs, underrepresentation of partially implantable hypoglossal nerve stimulation systems, and heterogeneity for adverse event reporting.

Heiser et al. (2022) compared hypoglossal nerve stimulation 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 hypoglossal nerve stimulation and 110 received PAP therapy. PAP therapy was initiated as first-line treatment in patients newly diagnosed with OSA, while hypoglossal nerve stimulation 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 hypoglossal nerve stimulation (8.1 ± 5.1 points versus 3.9 ± 6.8 points; p=0.042). In both groups, mean post-treatment AHI was significantly reduced (hypoglossal nerve stimulation: 8.1 ± 6.3/hour; PAP 6.6 ± 8.0/hour; p<0.001). Adherence to treatment after 12 months was higher with hypoglossal nerve stimulation but was not statistically significant. The authors concluded that patients treated with hypoglossal nerve stimulation 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 hypoglossal nerve stimulation 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 DISE. The primary outcome measures were AHI and ODI. At 12 months, 60% of patients 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 patients 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 to 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).

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): A position statement from the AAO-HNS (2021) regarding the treatment of OSA states: "Hypoglossal nerve stimulation therapy for OSA also results in improvement in quality of life, daytime sleepiness and reduction of AHI for select patients."

A position statement from the AAO-HNS (2019) regarding hypoglossal nerve stimulation for treatment of OSA states: "The American Academy of Otolaryngology-Head and Neck Surgery considers upper airway stimulation (UAS) via the hypoglossal nerve for the treatment of adult obstructive sleep apnea syndrome to be a safe and effective second-line treatment of moderate to severe obstructive sleep apnea in patients who are intolerant or unable to achieve benefit with positive pressure therapy."

Department of Veterans Affairs/Department of Defense (VA/DOD): The VA/DOD practice guideline for the management of chronic insomnia disorder and OSA states:

- "For treatment of obstructive sleep apnea in appropriate* patients (including with an apnea hypopnea index of 15 or greater per hour) who have not been successful with positive

airway pressure therapy, we suggest referral for evaluation for hypoglossal nerve stimulation therapy" (Weak for).
- "*Note FDA criteria for appropriate patients in the narrative."
- "At the time this guideline was updated, the United States Food and Drug Administration (FDA)'s criteria indicated that this device is cleared for use in adults 18 years of age or older with a body mass index <= 40 kg/m2 (although the device was originally tested in individuals with BMI <32 kg/m2) and a diagnosis of moderate to severe OSA with AHI 15-100 events per hour who have failed or are intolerant to PAP therapy. The FDA criteria indicate that this device should NOT be used in patients with central or mixed apnea that account for more than 25% of their total AHI, "a physical condition that would keep [the] upper airway stimulation from working well" (e.g. markedly enlarged tonsils), or conditions/treatments that would compromise or prevent neurological control the upper airway, as well as an individual who cannot operate the device remote or does not have the necessary assistance to operate it, are pregnant or plan to become pregnant, requires "magnetic resonance imaging other than what is specified in the magnetic resonance conditional labeling for the HGNS system," or have another implantable device that could have an unintended interaction with the HGNS device.(197) At the time the guideline was updated, the FDA also indicated that drug-induced sleep endoscopy should document the absence of complete concentric collapse at the level of the velopharynx of soft palate. (See FDA Site here for complete list)".

Literature Review (pediatric individual age 13-18 years with Down syndrome)

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

Liu et al. (2022) conducted a systematic review and meta-analysis to evaluate hypoglossal nerve stimulation in adolescents with Down syndrome and OSA. Of 92 articles identified, nine (106 patients) studies met the inclusion criteria. Age ranged from 10-21 years old. Follow-up periods ranged from two to 58 months. The Yu cohort study described below was the largest of the studies. Six of the studies included sample sizes of less than 10. The studies demonstrated that patients receiving hypoglossal nerve stimulation experienced a significant decrease in AHI (at least 50%). The pooled AHI was significantly lower for individuals following treatment (mean AHI reduction 17.43 events/hour, 95% CI 13.98 to 20.88 events/hour ($p<0.001$).

Yu and associates (2022) published the results of a prospective single group multicenter cohort study with one year follow up. The objective was to evaluate the safety and effectiveness of upper airway stimulation for adolescent participants with Down syndrome and severe OSA. The 42 participants 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. Participants were excluded if they had a central apnea contribution >25%; had a BMI >95th percentile; had a medical condition that would require future magnetic resonance imaging, had DISE findings consistent with circumferential palatal collapse; or had an AHI ≥50 events per hour. Participants were treated with upper airway stimulation (hypoglossal nerve stimulation). There was no comparator. Primary outcomes were safety and the change in the AHI from baseline to 12 months postoperatively. Secondary outcomes consisted of QOL surveys. Among the 42 participants, there was a mean (standard deviation[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 participants (30 of 41) had a 12-month AHI of less than 10 events per hour. The mean (SD) improvement in the OSA-18 QOL total score was 34.8 (20.3) (95% CI, −42.1 to −27.5), and the mean (SD) improvement in the ESS 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 participants (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 participants (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 Down syndrome are the best candidates for this procedure.

Stenerson et al. (2021) conducted a 44-month follow-up of four participants that had participated in an earlier pilot study. 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 participants, 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, reductions of at least 50% in AHI over the course of follow-up were maintained by all four participants. 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 QOL scores was observed in three of the four participants. The study was limited by a small sample size of four participants. While 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 QOL. The authors acknowledged that suitability of this device may differ in pediatric patients with Down syndrome who are less communicative or whose caregiver support is less involved. The authors concluded that while hypoglossal nerve stimulation continued to effectively control OSA in children with Down syndrome 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.

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.

Literature Review

There is insufficient evidence to demonstrate the safety and efficacy of atrial overdrive pacing in the treatment of 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. The effect on OSA 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 RCTs to determine the effects of atrial overdrive pacing on sleep apnea syndrome (n=129). Atrial overdrive pacing, as compared to non-pacing, reduced the 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 OSA syndrome-predominant trials. It was also unclear whether AHI was reduced. The authors concluded that the role of atrial overdrive pacing in OSA syndrome remains unclear.

Professional Societies/Organizations

American College of Cardiology Foundation (ACCF)/American Heart Association (AHA)/Heart Rhythm Society (HRS): Based on data from a small retrospective trial and subsequent RCTs, ACCF/AHA/HRS guidelines for device-based therapy of cardiac rhythm abnormalities state: "Whether cardiac pacing is indicated among patients with obstructive sleep apnea and persistent episodes of bradycardia despite nasal continuous positive airway pressure has not been established" (Epstein et al., 2013).

Cautery-Assisted Palatal Stiffening Operation (CAPSO)

Cautery-assisted palatal stiffening operation (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.

Literature Review

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.

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 also 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.

Injection Snoreplasty

Injection snoreplasty is a proposed treatment for snoring that involves the injection of a hardening agent, e.g., sodium tetradecyl sulfate, into the upper palate. Following the injection, scar tissue is reported to pull the uvula forward to eliminate palatal flutter associated with snoring.

Literature Review

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, also known as the Pillar procedure, is a minimally invasive treatment purported to reduce snoring and treat OSA. The procedure involves placing three small woven polyester implants into the soft palate. The fibrotic tissue that forms around the implants may stiffen the soft palate, reduce the vibration that causes snoring, and help prevent collapse of the airway that leads to OSA.

U.S. Food and Drug Administration (FDA)

On July 28, 2004, the Pillar Palatal Implant System (Restore Medical Inc.) received FDA 510(k) clearance. The FDA 510(k) summary states, "The Pillar™ Palatal Implant System is intended for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (Obstructive Sleep Apnea)."

On February 10, 2012, the Pillar Palatal Implant System (Medtronic Xomned, Inc.) received FDA 510(k) clearance. The FDA 510(k) summary states, "The Pillar Palatal Implant System is intended for use in stiffening the soft palate tissue which may reduce the severity of snoring in some individuals."

Device or Product	Identifier	Manufacturer	Decision Date
Pillar Palatal Implant System	K040417	Restore Medical Inc.	07/28/2004
Pillar Palatal Implant System	K110623	Medtronic Xomned, Inc.	02/10/2012

*FDA product code: LRK

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

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

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 ESS ($p<0.001$) and AHI ($p=0.002$) 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 multi-level 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 ($p<0.0001$). Mean ESS decreased from 9.7 ± 3.9 to 7.0 ± 3.3 ($p<0.0001$). Limitations of the study include retrospective design, lack of long-term outcomes, and 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/m^2, 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.

Radiofrequency Volumetric Tissue Reduction (RFVTR) of the Soft Palate, Uvula, or Tongue Base (e.g., Coblation®, Somnoplasty®)

Radiofrequency volumetric tissue reduction (RFVTR) of the soft palate, uvula, or tongue base (e.g., Coblation, Somnoplasty) is a procedure used to remove redundant tissue from the soft palate, uvula, or tongue base.

U.S. Food and Drug Administration (FDA)

Electrosurgical cutting and coagulation devices used for RFVTR are numerous and include the ENTec™ ReFlex™ Wand (ArthroCare Corp.) and the Somnoplasty System (Somnus Medical Technologies).

Device or Product	Identifier	Manufacturer	Decision Date
Somnoplasty System	K971450	Somnus Medical Technologies, Inc.	7/17/1997
Somnoplasty System	K973618	Somnus Medical Technologies, Inc.	12/19/1997
Somnoplasty System	K982717	Somnus Medical Technologies, Inc.	11/02/1998
ENTec Reflex Wand	K000036	Arthrocare Corp.	02/04/2000
ENTec Reflex Wand	K000778	Arthrocare Corp.	05/03/2000

*FDA product code: GEI

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

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

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 QOL after radiofrequency ablation.

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): A position statement from the AAO-HNS (2014) regarding submucosal ablation of the tongue base for OSA syndrome states:

- "Adult patients with mild to severe obstructive sleep apnea (OSA) can be successfully treated with submucosal radiofrequency tongue base ablation."
- "The majority of studies demonstrating effectiveness of tongue base submucosal radiofrequency ablation (RFA) have been performed in patients with mild to moderate OSA and without morbid obesity, often as part of multilevel pharyngeal surgical therapy."

Tongue-Base Suspension (e.g., AIRvance™ System, ENCORE™ Tongue Suspension System)

Minimally invasive tongue-base suspension devices (e.g., the AIRvance System, ENCORE Tongue Suspension System) are purported to treat OSA by stabilizing the tongue base and/or hyoid bone using bone anchors or screws combined with sutures to prevent airway collapse during sleep.

U.S. Food and Drug Administration (FDA)

Devices for tongue-base suspension include the Encore™ Suspension System (Siesta Medical, Inc.) and the AIRvance™ Bone Screw System (Medtronic), formerly the Repose Bone Screw System (Influence, Inc.)

The most recent FDA 510(k) clearance for the Encore Suspension System (K213159) states, "The Encore System is intended for anterior advancement of the tongue base and hyoid suspension. It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring."

The most recent FDA 510(k) clearance for the AIRvance™ Bone Screw System (K122391) states, "The AIRvance™ Bone Screw System is intended for 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 suture. It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring. The AIRvance™ Bone Screw System is also suitable for the performance of a hyoid suspension procedure which can be used in combination with other procedures for the treatment of obstructive sleep apnea (OSA). It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring."

Device or Product	Identifier	Manufacturer	Decision Date
Repose Bone Screw System	K981677	Influence, Inc.	8/27/1999
AlRvance Bone Screw System	K122391	Medtronic Xomed, Inc.	01/10/2013
Encore System	K183310	Siesta Medical, Inc.	5/09/2019
Encore System	K201238	Siesta Medical, Inc.	10/02/2020
Encore System	K213159	Siesta Medical, Inc.	12/22/2021

*FDA product code: LRK; ORY

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review

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.

ECRI published an evidence analysis regarding the Encore Suspension System for treating OSA. The analysis selection criteria included studies that reported on ≥ 10 individuals treated with the Encore Suspension System. Studies with outcomes that could not be attributed to the Encore Suspension System (e.g., studies pooling devices) were excluded. The objective of the analysis was to determine how well the Encore Suspension System worked compared to other OSA treatments. Three retrospective before-and-after studies were identified and included in the analysis: Valika et al. (2024) (n=30), Van Tassel et al. (2023) (n=39), and Ong et al. (2017) (n=19). ECRI concluded there were no published studies that compared the Encore Suspension System with other minimally invasive surgical techniques or alternative suspension systems. The three before-and-after studies suggested the Encore Suspension System improves symptoms for individuals with moderate-to-severe OSA. However, the available studies were small, at a high risk of bias, and differed in surgical approach. The findings may not be generalizable. Limitations in the body evidence include no independent control group, small sample size, retrospective design, data not available on comparisons of interest, single medical center or health system design, longer follow-up needed for outcome measures, and lack of data for some outcomes, e.g., QOL (ECRI, 2025).

Bostanci and Turhan (2016) conducted a systematic review to evaluate existing research into the effectiveness and safety of two tongue base suspension techniques (Repose® system and modified tongue base suspension) with or without UPPP in OSA. Seven studies including 113 patients met the eligibility criteria for tongue base suspension as a stand-alone procedure. Four of seven studies, including 62 patients used the Repose, and three studies, including 51 patients used the modified tongue base suspension. 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 tongue base suspension combined with UPPP. Seven of ten studies, including 176 patients, used the Repose, and three studies, including 124 patients, used the modified tongue base suspension. The success rates in this group were similar between the modified tongue base suspension (73.4%) and Repose (67.6%) ($p=0.341$). When aggregate data of 413 patients were compared, the modified tongue base suspension was found to be associated with significantly higher success rates (73.7% versus 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 OSA 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 multi-level 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.

Professional Societies/Organizations

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS):
Recommendations from a position statement from the AAO-HNS (2016) regarding tongue suspension state: "Tongue based suspension is effective and even comparable to genioglossus advancement. It should, therefore, not be deemed investigational when considered as part of a comprehensive approach in the medical and surgical management of symptomatic adult patients with mild OSAHS and adult patients with moderate and severe OSAHS who have evidence of tongue base or associated hypopharyngeal obstruction. Results appear to diminish in obese patients and this technique should receive a weaker recommendation for these patients."

Transpalatal Advancement Pharyngoplasty (TPAP)

Transpalatal advancement pharyngoplasty (TPAP) is a surgical procedure purported to treat OSA by enlarging the space behind the soft palate. The procedure involves removing a small portion of the hard palate and then advancing and securing the soft palate to the surrounding structures to reduce airway obstruction (Sarber, et al., 2021).

Literature Review

The evidence evaluating TPAP is limited, consisting primarily of retrospective reviews. There is insufficient evidence in the published medical literature to determine the safety and efficacy of TPAP or to determine how it compares to other treatment options for OSA.

Volner et al. (2017) conducted a systematic review and meta-analysis to evaluate if AHI and lowest oxygen saturation (LSAT) improve after 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 recommended additional studies, especially prospective studies. Research comparing TPAP procedures with palatal advancement are needed to determine the optimal role for this procedure.

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 disproportionally 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 that the delayed diagnosis is not due to atypical presentation.

OSA effects 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).

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Revision Details

Type of Revision	Summary of Changes	Date

Annual review	• Revised policy statement for drug-induced sleep endoscopy (DISE) in adults. • Revised policy statement for uvulectomy. • Revised policy statement for implantable upper airway hypoglossal nerve stimulation device in adults. • Removed policy statement for tongue implant (e.g., ReVENT® Sleep Apnea System).	3/15/2026
Annual review	• 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	• 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