Obstructive and Central Sleep Apnea Treatment

Policy Number: 2026T0525WW
Effective Date: November 1, 2026

➲ Instructions for Use

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Related Commercial/Individual Exchange Policies

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements
- Orthognathic (Jaw) Surgery
- Outpatient Surgical Procedures – Site of Service
- Sleep Studies

Community Plan Policy

- Obstructive and Central Sleep Apnea Treatment

Medicare Advantage Policy

- Sleep Apnea Surgical Treatments

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

Obstructive Sleep Apnea

Diagnosis of Obstructive Sleep Apnea for Nonsurgical or Surgical Treatment

- An individual presenting with symptoms of Obstructive Sleep Apnea (OSA) has been seen for an evaluation (in person or via telemedicine) with a qualified physician or with an Advanced Practice Provider working under the direct supervision of a physician prior to beginning treatment
- A qualified physician or an Advanced Practice Provider working under the direct supervision of a physician will diagnose OSA and recommend the course of treatment

Nonsurgical Treatment

Removable Oral Appliances are proven and medically necessary for treating OSA meeting the diagnosis requirements above and which has been documented by a sleep study (e.g., Polysomnography (Attended), Home Sleep Apnea Testing). Refer to the Medical Policy titled Sleep Studies for further information.

Oral Appliance therapy may be an effective alternative to failed Positive Airway Pressure (PAP) therapy. Documentation from the individual's treating physician or Advanced Practice Provider that PAP therapy resulted in no therapeutic efficacy, or an individual is intolerant or has refused is required.

For medical necessity clinical coverage criteria for removable Oral Appliances, refer to the InterQual® CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices.

Click here to view the InterQual® criteria.

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Other Nonsurgical Procedures

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Devices for treating Positional OSA
- Nasal dilator devices for treating OSA
- Intranasal expiratory resistance valve (e.g., Bongo Rx)
- Prefabricated Oral Appliance/device
- Nonsurgical electrical muscular training
- Mandibular vertical repositioning devices (e.g., Slow Wave)
- Morning repositioning devices
- Epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime appliance)]
- Advanced Lightwire Functional appliances

Surgical Treatment

Uvulopalatopharyngoplasty, mandibular osteotomy, and maxillomandibular osteotomy and advancement (MMA) are proven and medically necessary in an adult individual when all the following criteria are met:

- Moderate to severe OSA meeting the diagnosis requirements above [Apnea-Hypopnea Index (AHI) ≥ 15 or Respiratory Disturbance Index ≥ 15], as determined by Polysomnography (Attended)*
- Excessive daytime sleepiness documented with an Epworth Sleepiness Scale of > 10 or with another validated tool
- PAP therapy resulted in no therapeutic efficacy or individual's refusal or intolerance

In addition, the following criteria need to be met:

- For MMA, craniofacial disproportion or deformities with evidence of maxillomandibular deficiency
- For mandibular osteotomy, retrolingual or lower pharyngeal function obstruction

Implantable hypoglossal nerve stimulation with a U.S. Food and Drug Administration (FDA)–approved device is proven and medically necessary in an adult individual with moderate to severe OSA meeting the diagnosis requirements above when all the following criteria are met:

- Body Mass Index of ≤ 40 kg/m^2; and
- AHI of ≥ 15 and ≤ 100, as determined by Polysomnography (Attended)*; and
- Total AHI of < 25% for central and mixed Apneas, as evaluated by attended polysomnography; and
- Absence of a complete blockage or complete concentric collapse of the soft palate, confirmed by drug-induced sleep endoscopy; and
- PAP therapy resulted in no therapeutic efficacy or individual's refusal or intolerance; and
- Used in accordance with FDA guidelines

Implantable hypoglossal nerve stimulation with an FDA-approved device is proven and medically necessary in adolescents aged 10 to 18 years with Down syndrome when all the following criteria are met:

- Diagnosis of severe OSA meeting the diagnosis requirements above and [as determined by a Polysomnogram (Attended)* and an AHI ≥ 10 and Respiratory Disturbance Index ≤ 50 events per hour]; and
- Body Mass Index of < 95th percentile for age; and
- Total AHI of < 25% for central and mixed Apneas; and
- Contraindication for or not effectively treated with a prior adenotonsillectomy; and
- Confirmed failure or intolerance of PAP therapy, despite attempts to improve adherence; and
- Absence of tracheostomy use during sleep; and
- Absence of a complete blockage or concentric collapse of the soft palate level, confirmed by drug-induced sleep endoscopy; and
- Individual and caregiver refusal of an MMA procedure for nonconcentric palatal collapse; and
- Used in accordance with FDA guidelines

*Polysomnography should be repeated if there has been clinically significant weight loss or gain, changes in cardiovascular disease, or persistent or recurrent symptoms since the last study (Caples et al., 2021).

Other Surgical Procedures

The following surgical procedures are unproven and not medically necessary for treating OSA due to insufficient evidence of efficacy (not an all-inclusive list):

- Lingual suspension – Also referred to as tongue stabilization, tongue stitch, and tongue fixation
- Isolated hyoid myotomy

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- Stand-alone uvulectomy
- Transoral robotic surgery
- Distraction osteogenesis for maxillary expansion
- Radiofrequency ablation of the soft palate and/or tongue base

Central Sleep Apnea

Implantable phrenic nerve stimulation devices (e.g., the remedē® System) for the treatment of Central Sleep Apnea are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

Removable Oral Appliances for treating Central Sleep Apnea are unproven and not medically necessary due to insufficient evidence of efficacy.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

Advanced Practice Providers: Nonphysician direct care providers such as physician assistants and advanced practice registered nurses (Sarzynski and Barry, 2019).

Apnea: The cessation of airflow (≥ 90% decrease in Apnea sensor excursions compared with baseline) lasting at least 10 seconds. Apneas are classified as obstructive, mixed, or central, based on the pattern of respiratory effort.
- An obstructive Apnea is associated with continued or increased inspiratory effort throughout the entire period of absent airflow
- A central Apnea is associated with absent inspiratory effort throughout the entire period of absent airflow
- Mixed Apneas are associated with absent inspiratory effort in the initial portion of the event, followed by resumption of inspiratory effort in the second portion of the event

(American Academy of Sleep Medicine Scoring Manual, 2023)

Apnea-Hypopnea Index: The number of Apneas plus the number of Hypopneas during the entire sleeping period, times 60, divided by total sleep time in minutes; unit: event per hour (American Academy of Sleep Medicine Scoring Manual, 2023).

Body Mass Index: A person's weight in kilograms divided by the square of height in meters. Body Mass Index (BMI) can be used as a screening tool but is not diagnostic of the body fatness or health of an individual (Centers for Disease Control and Prevention, 2017).
- The National Heart, Lung, and Blood Institute's Practical Guide Identification, Evaluation, and Treatment of Overweight and Obesity in Adults classifies the ranges of BMI in adults as follows:
- < 18.5 kg/m^2 – Underweight
- 18.5 to 24.9 kg/m^2 – Normal Weight
- 25 to 29.9 kg/m^2 – Overweight
- 30 to 34.9 kg/m^2 – Obesity Class I
- 35 to 39.9 kg/m^2 – Obesity Class II
- ≥ 40 kg/m^2 – Obesity Class III

In a clinical practice guideline, the American Academy of Pediatrics (Hampl et al., 2023) classifies severe obesity as follows:
- Class II obesity – ≥ 120% of the 95th percentile height or a BMI of ≥ 35 kg/m^2 to < 40 kg/m^2, whichever is lower based on age and sex
- Class III obesity – ≥ 140% of the 95th percentile or a BMI of ≥ 40 kg/m^2, whichever is lower based on age and sex

Central Sleep Apnea: Central Sleep Apnea syndromes are characterized by sleep-disordered breathing that is associated with diminished or absent respiratory effort, coupled with the presence of symptoms, including excessive daytime sleepiness, frequent nocturnal awakenings, or both (Aurora et al., 2012).

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Epworth Sleepiness Scale: The Epworth Sleepiness Scale is an eight-item questionnaire that is used to determine the level of a person's daytime sleepiness. The Epworth Sleepiness Scale is based on an individual's assessment of the likelihood of falling asleep in certain situations that are commonly encountered in daily life. Refer to the following website for further information: http://epworthsleepinessscale.com/about-the-ess/.

Home Sleep Apnea Testing: The use of unattended diagnostic studies to assess for Obstructive Sleep Apnea (OSA) without the determination of sleep stage. The term specifies the condition being assessed (i.e., sleep Apnea) by current technology, without implying that sleep quality, staging, or time is determined. Not all such studies are performed at home; however, that is where the vast majority of individuals undergo these tests (American Academy of Sleep Medicine Style Guide, 2015). Adequate Home Sleep Apnea Testing occurs over a minimum of 4 hours and includes a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry (Kapur et al., 2017). Home Sleep Apnea Testing is also referred to as out-of-center sleep testing and portable monitoring.

Hypopnea: An abnormal respiratory event that lasts at least 10 seconds and is associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or an event that is associated with an arousal (American Academy of Sleep Medicine Scoring Manual, 2023).

Obstructive Sleep Apnea: The American Academy of Sleep Medicine defines OSA as a sleep-related breathing disorder that involves a decrease or complete halt in airflow, despite an ongoing effort to breathe.

- OSA severity is defined as:
- Mild for Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of ≥ 5 and < 15
- Moderate for AHI or RDI of ≥ 15 and ≤ 30
- Severe for AHI or RDI of > 30/hour

Oral Appliance: A device that is inserted into the mouth for treatment of snoring or OSA (Berry, 2012). These devices can be prefabricated (ready made) or custom made.

Polysomnogram (Attended): A laboratory-based sleep study that uses multiple channels to record a wide range of physiological information, including brain activity, eye movements, body movements, breathing, and heart rate (American Thoracic Society, 2015; updated 2019).

Positional Obstructive Sleep Apnea: The American Academy of Sleep Medicine defines Positional OSA as a lower AHI in the nonsupine position than in the supine position (deVries, 2015).

Positive Airway Pressure: A process in which an air pump (fan-driven or turbine system) draws in external, filtered air and delivers pressurized airflow to keep an individual's airway open. These devices are divided into four basic types, depending on their pressure delivery system:

- Continuous Positive Airway Pressure: Delivers a steady, fixed flow of air pressure on inhalation
- Bilevel Positive Airway Pressure: Delivers a higher flow of air pressure on inhalation than exhalation
- Autotitrating Positive Airway Pressure: Automatically changes the flow of air pressure (continuous Positive Airway Pressure or bilevel Positive Airway Pressure), based on an individual's breathing patterns
- Adaptive servoventilation: Uses a servocontroller to automatically adjust the flow of air pressure by breath-by-breath analysis to maintain a steady minute ventilation

(Kushida et al., 2008)

Respiratory Disturbance Index: The number of Apneas plus the number of Hypopneas plus the number of respiratory effort-related arousals during the entire sleeping period, times 60, divided by total sleep time in minutes; unit: events per hour (American Academy of Sleep Medicine Scoring Manual, 2023).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

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Coding Clarification: HCPCS code E0486 applies to the custom fabricated oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable and includes fitting and adjustment. Dental services (e.g., CDT codes D9947, D9948, and D9949) are excluded from coverage under the medical plan; the member specific benefit plan document must be referenced prior to determining any coverage decision.

CPT Code	Description
0964T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; single arch, without mandibular advancement mechanism
0965T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, non-fixed hinge mechanism
0966T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, fixed hinge mechanism
21142	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, without bone graft
21199	Osteotomy, mandible, segmental; with genioglossus advancement
21206	Osteotomy, maxilla, segmental (e.g., Wassmund or Schuchard)
21685	Hyoid myotomy and suspension
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
33277	Insertion of phrenic nerve stimulator transvenous sensing lead (List separately in addition to code for primary procedure)
33278	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)
33279	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only
33280	Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
33281	Repositioning of phrenic nerve stimulator transvenous lead(s)
33287	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator
33288	Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)
41512	Tongue base suspension, permanent suture technique
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
41599	Unlisted procedure, tongue, floor of mouth
42140	Uvulectomy, excision of uvula
42145	Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)
64568	Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

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CPT Code	Description
93150	Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming
93151	Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
93153	Interrogation without programming of implanted phrenic nerve stimulator system

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HCPCS Code	Description
A7049	Expiratory positive airway pressure intranasal resistance valve
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
E0490	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
E1399	Durable medical equipment, miscellaneous
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8697	External accessory for use with implantable phrenic nerve stimulation device, replacement, each
S2080	Laser-assisted uvulopalatoplasty (LAUP)
S2900	Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)

Description of Services

Obstructive Sleep Apnea (OSA) is a breathing disorder that is defined by episodes of decreased or complete cessation of airflow during sleep. In OSA, airflow is obstructed when the muscles in the back of the throat fail to keep the airway open. Nocturnal respiration in individuals with OSA is characterized by episodes of Apnea (breathing cessation) and Hypopnea (marked reduction in breathing volume). The signs and symptoms of untreated OSA include excessive daytime sleepiness, loud snoring, nocturnal choking, Apneas or choking witnessed by bed partner, unrefreshing sleep, morning headaches, reduced libido, and enuresis. The physiological effects of untreated OSA include fluctuating blood oxygen levels, increased heart rate, chronic daytime hypertension, and impaired glucose tolerance/insulin resistance.

Central Sleep Apnea (CSA) is distinguished by a temporary interruption of neural output from the respiratory control center, resulting in loss of respiratory stimulation and airflow cessation. The International Classification of Sleep Disorders identifies six different forms of CSA. However, the underlying pathophysiology of CSA is due to either post hyperventilation central Apnea, which may be triggered by a variety of clinical conditions, or central Apnea secondary to hypoventilation, which has been described with opioid use hypoventilation. This condition occurs frequently in individuals with heart failure and increases the risk for morbidity and mortality. It is estimated that CSA may be present in 30% to 50% of individuals with heart failure. Currently available treatments for CSA are not widely accepted because of sparse

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effectiveness data, individuals' poor adherence, and potential safety risks. However, implantable neurostimulation devices have been studied for the treatment of CSA.

Diagnosis and evaluation of sleep Apnea syndrome is determined through a Polysomnogram or limited channel testing. Treatment for OSA includes lifestyle modifications (weight loss and avoidance of alcohol or other agents that decrease upper airway patency), positional therapy, Positive Airway Pressure (PAP), Oral Appliance therapy, electrostimulation devices, and surgery. PAP therapy may use any one of the following techniques: continuous PAP, automatic PAP, bilevel PAP, and variable PAP.

Nonsurgical Oral Appliances, worn during sleep, can be an effective treatment option for snoring and OSA. These devices work by keeping the airway open in one of three ways: by pushing the lower jaw forward (a mandibular advancement device or MAD), by preventing the tongue from falling back over the airway (a tongue-retaining device), or by combining both mechanisms. A known side effect with the use of a nighttime nonsurgical Oral Appliance (i.e., sleep Apnea appliance) for OSA is occlusal discrepancy. Morning repositioning devices, which are used after removal of the nighttime Oral Appliance, guide the maxillary and mandibular teeth back into their normal alignment. However, it must be noted that despite the widespread use of this technique, no evidence to date has demonstrated its effectiveness (American Academy of Dental Sleep Medicine, 2017). Epigenetics is an area of science that examines how external factors affect gene activity without altering DNA sequence. Evidence suggests that bone remodeling may be epigenetically regulated. Intraoral devices are available that assert that this can change the jaw shape to treat and cure multiple conditions, including OSA. The Advanced Lightwire Functional appliance is a cranial osteopathy-based orthodontic system that uses a custom appliance made of light, flexible wire. Proponents of this device state that it applies subtle forces that closely mimic the natural growth and development process and that it can widen and/or reposition the jaws.

A nasal dilator operates by mechanically opening the nasal passages either externally or internally. External nasal dilators, also known as nasal strips, are positioned just below the bone of the nose and pull the nasal passages open. Internal nasal dilators come in a variety of shapes and sizes and are positioned just inside the nose to prop the nostrils open.

A nasal expiratory PAP device is a one-way valve that attaches to the nostrils before sleep. These valves use the sleeper's own breathing to create positive end-expiratory pressure, with minimal resistance. This "high end-expiratory pressure leads to upper airway dilation with subsequent tracheal traction and increased lung volumes during exhalation, thereby making the upper airway more resistant to narrowing/closure during ensuing inspiration" (Lorenzi-Filho et al., 2017). These devices are often reusable, comfortable, and easy for the individual to use.

Positional therapy for OSA may be an effective method for short-term treatment in individuals in whom OSA is improved by sleeping on the side. Devices that support positional therapy include but are not limited to vibrating devices, pillows, tennis balls, adjustable beds, and chest vests that prevent the individual from sleeping in the supine position.

A variety of surgical options are available to treat OSA. The intention of surgery is to create a more open airway so that obstructions are less likely to occur.

Currently, one hypoglossal nerve stimulation device is cleared by the US Food and Drug Administration. The Inspire® Upper Airway Stimulation device (Inspire Medical Systems, Inc.) treats moderate to severe OSA in individuals who are unable or unwilling to use PAP therapy and may or may not be surgical candidates. The device is implanted subcutaneously in the chest, with one lead attached to the individual's hypoglossal nerve at the base of the tongue. The lead in the chest consists of a pressure sensor that detects respiration, and when this is decreased, the hypoglossal nerve is stimulated, and the tongue moves forward, opening the airway.

Clinical Evidence

Nonsurgical Treatment

Devices for Treating Positional Obstructive Sleep Apnea

There are a variety of devices that are used for treating positional obstructive sleep apnea (OSA). The available literature that addresses these devices is conflicting or inconclusive; thus, future studies are warranted to demonstrate their safety and efficacy.

In a Health Technology Assessment, Hayes reflects an overall low-quality body of evidence for the use of NightBalance for the treatment of positional OSA. The evidence included six studies: two randomized controlled trials (RCTs), two RCTs with a crossover design, and two studies with pre- and posttest designs. Overall, the evidence lacked comparative studies

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and long-term efficacy. No new studies were identified in the 2024 annual review that would change this conclusion (Hayes; updated 2024).

In 2025, Gao et al. (2025) conducted a meta-analysis of 19 RCTs, comprising 1,231 individuals, to compare the safety and efficacy of sleep positional therapy (SPT) with those of continuous positive airway pressure (CPAP), oral appliance therapy (OAT), and placebo. Nine were crossover RCTs, and 10 were parallel RCTs. Eight compared SPT with placebo, five compared SPT with OAT, and six compared SPT with CPAP. Of the 1,231 individuals, 649 were in the SPT group, 205 were in the placebo group, 222 were in the OAT group, and 155 were in the CPAP group. Interventions for SPT included multiple devices and positional change devices. The results for the effectiveness of SPT compared with that of placebo showed that SPT had a greater reduction in the Apnea-Hypopnea Index (AHI) in the supine position than placebo, with a mean difference of -7.46 (95% CI, -11.42 to -3.49), although considerable heterogeneity was observed among the studies. No significant differences were seen in overall AHI, nonsupine AHI, and total sleep time, suggesting that the benefit with SPT may be limited to individuals with supine-related OSA. No changes were noted in other sleep parameters. The results for SPT vs OAT showed that SPT did not reduce overall AHI or AHI in the supine position and other sleep-related indices; SPT showed greater improvements in Arousal Index than OAT, with a significant mean reduction of -7.11, suggesting that SPT may offer better sleep continuity by reducing nighttime awakenings. The results for SPT compared with CPAP showed that CPAP is superior in reducing overall AHI and oxygenation. For the evaluation of sleep architecture, the results were inconsistent and not uniform across all sleep stages. No significant differences were found in mean SaO2 or minimum SaO2. The authors concluded that SPT is a safe and viable alternative for managing OSA, especially for individuals with positional OSA or CPAP intolerance. These results are limited by a high degree of heterogeneity, including the type of study design (including severity of OSA and comorbid conditions), types of SPT devices, intervention protocols, and follow-up times. Furthermore, only seven RCTs had a low risk of bias. Additional research that addresses the substantial heterogeneity is needed to validate these findings.

In a 2021 evidence analysis on the NightBalance Lunoa (Philips Respironics, Inc.) vs OAT or CPAP for positional OSA, it was concluded that based on the results of three RCTS, there are too few data to draw conclusions on safety and efficacy. Limitations of the evidence include different treatments, resulting in different outcomes that are not generalized across all studies, as well as small sample sizes and a high risk of bias.

In a Cochrane review of RCTs, Srijithesh et al. (2019) compared the efficacy of positional therapy vs that of CPAP and positional therapy vs inactive control (sham intervention or no positional therapy intervention) in people with OSA. Eight studies, with 323 randomized individuals, met the inclusion criteria. The comparison between positional therapy and CPAP included 72 individuals, while the comparison between positional therapy and the inactive control included 251 individuals. Three studies used supine vibration alarm devices, while five studies used physical positioning. The authors found that while positional therapy may have better adherence by individuals, CPAP has a greater effect on the improvement in the AHI. The evidence was low to moderate, and all studies were of short-term duration; therefore, future long-term studies are needed for long-term outcomes and efficacy.

A multicenter trial randomized 99 participants with mild to moderate positional OSA to either a sleep position trainer group or one with OAT (de Ruiter et al., 2018, included in the Hayes report above). Sleep position training is a newer option for treating positional OSA, and the authors' goal was to investigate the long-term efficacy of and adherence and quality of life (QOL) with this device. Eligible participants had a diagnosis of mild to moderate positional OSA (AHI of 5-30) and spent 10% to 90% of their sleep time in the supine position. The SPT group used the NightBalance device, which was worn across the chest using a neoprene strap. The active comparator was a SomnoDent Flex device, custom made by SomnoMed, which included a blue chip for adherence. Analysis of the data indicated that the AHI and Oxygen Desaturation Index (ODI) were significantly reduced in both treatment groups at the 3- and 12-month follow-up visits, along with similar results for adherence to device usage in both groups. The main limitation of this study is the higher dropout rate during the study that did not allow analysis of the complete randomized sample.

Barnes et al. (2017) conducted a systematic review and meta-analysis on positional modification techniques in individuals with supine OSA. Seven studies, with 108 individuals, met the inclusion criteria in comparing any type of positional therapy (e.g., vibratory vests, foam backpacks, tennis balls) with any other intervention. For positional techniques compared with nonstandard therapy, four studies included in the meta-analysis showed significant reduction in the AHI that favored the positional techniques. For positional techniques compared with CPAP therapy, two studies showed significant reduction in the AHI that favored CPAP. One study showed a significant reduction in the AHI that favored the sleep position trainer compared with a tennis ball vest. Additionally, the evidence suggested that there was no significant effect on sleepiness or sleep efficiency when position modification therapy was compared with no treatment or the CPAP treatment. Although it was identified that individuals have greater adherence to positional techniques than with CPAP in the short term, the authors found that long-term results remain unclear, specifically for electronic vibratory devices. In

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addition, CPAP is more effective at reducing the AHI. Future studies should include multiple positional devices and include an adequate number of individuals, a comparison group, and long-term follow-up.

Nasal Dilators

The available evidence for nasal dilators is conflicting but tends to support the ineffectiveness of these devices. To prove a benefit with nasal dilators, future research should demonstrate the clinical utility and long-term safety and efficacy of these devices.

Suzuki et al. (2022) conducted a study in 10 male participants and evaluated the airflow rate of a new nasal breathing stent (NBS) against that of existing nasal dilators. The following comparator dilators were used: (1) Max-Air Nose Cones® and Mute® with hole for internal nasal use and (2) Breathe Right®, an external nasal dilator. The NBS design expands the nasal valve by pressing the depressor septi at the joint and is designed to facilitate airflow via the enhanced diameter differences at the entry and exit sections. Airflow movement was filmed with and without the appliance; a high-speed camera was used to measure and capture airflow velocity when the appliance was used. The authors found that the mean velocity was significantly higher with the NBS than with the other appliances used. Limitations include a small sample size and lack of long-term OSA-specific outcomes. While this new device shows promise, further investigation in individuals with OSA is necessary to examine the effects of NBS compared with those of an oral appliance or CPAP.

Gelardi et al. (2019) studied 19 adults with OSA and whether the use of an internal nasal dilator was able to significantly reduce the AHI and ODI. Subjective parameters were evaluated by the participants and included perception of nasal obstruction, sleep quality, and olfaction; these were all measured by a visual analog scale (VAS). The VAS scores ranged from 0 for a completely blocked nose to 10, which indicated a completely patent nose. An additional evaluation of smell, quality of sleep, and satisfaction was performed. Daytime sleepiness was evaluated by the Epworth Sleepiness Scale (ESS); an ESS score of ≥ 10 was considered excessive daytime sleepiness. Cardiorespiratory nocturnal monitoring was performed in all participants. Oxyhemoglobin saturation, heart rate, body posture, oral-nasal air flow, snoring sounds, and thoracic and abdominal movements were recorded in detail. Each participant was given the Nas-air® device, with appropriate instruction for use. The results indicated that the use of Nas-air significantly reduced the AHI values (38.7 ±30 vs 31.1 ±27.4; p = 0.000) and ODI scores (36.4 ±30.6 vs 29.0 ±26.4; p = 0.001). In addition, the use of Nas-air significantly increased the Restoring Sleep score (54.8 ±26.2 vs 73.3 ±21.7; p = 0.000). The authors concluded that the results showed that Nas-air is a new internal nasal dilator that is potentially capable of significantly improving respiratory outcomes and sleep quality in individuals with OSA. However, the study has some limitations, including the lack of comparison with established treatments, open-label study design, lack of follow-up, and low number of enrolled participants. Thus, further studies should be conducted to demonstrate the clinical utility of this device.

In a systematic review and meta-analysis, Camacho et al. (2016) evaluated internal (NoZovent) and external (Breathe Right strips) nasal dilators as treatment for OSA. Five studies were found for internal dilators and nine studies for external dilators. Twelve of the 14 studies showed no significant change in the AHI with the use of nasal dilators. Furthermore, the meta-analysis of the combined studies did not show any benefit with the device. The essential limitation of this study is the lower quality of published studies that evaluated nasal dilators. Most studies were individual case-control studies or prospective case series that often had smaller sample sizes, a lack of randomization, and other significant drawbacks. Although nasal dilators have demonstrated improved nasal breathing, they have not shown improvement in OSA outcomes, except with mild improvement in apnea when internal nasal dilators were used.

Intranasal Expiratory Resistance Valve

The evidence for intranasal expiratory resistance valves is limited and of low quality; these devices vary, and the studies have small sample sizes. To prove a benefit with these appliances, future research should demonstrate the clinical utility and long-term safety and efficacy of these devices. As of 2020, the Provent device is no longer manufactured.

In a randomized, partially blinded, placebo-controlled trial, Rossi et al. (2013) evaluated the efficacy of the Provent nasal device for preventing the recurrence of OSA following CPAP withdrawal in participants with moderate to severe OSA. The goal of the study was to determine if participants with OSA could occasionally substitute the Provent device for their CPAP. Overall, 67 participants with OSA who were receiving CPAP were randomized to one of three groups for 2 weeks: continuing CPAP (n = 23), active Provent (n = 22), or placebo Provent (n = 22). The three groups were similar at baseline, and their mean AHI before CPAP treatment was 38 events per hour. The primary outcomes included for the active Provent vs placebo Provent were OSA severity and ODI, AHI, and ESS scores. Secondary outcomes for the active Provent vs placebo Provent included the ODI from ambulatory pulse oximetry and blood pressure (BP). For CPAP vs active Provent or CPAP vs placebo Provent, secondary outcomes included the ODI/AHI, the ESS, and BP. OSA recurred in the active Provent and placebo Provent groups, and no significant difference was observed in the ODI, AHI, and ESS between active Provent and placebo Provent at 2 weeks. The ODI from ambulatory pulse oximetry and BP at 2 weeks

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were no different in the active Provent vs placebo Provent groups. The ODI, the AHI, and BP, but not the ESS, were significantly higher in the active Provent and placebo Provent groups than in the CPAP group. The authors concluded that Provent cannot be recommended as an alternative short-term therapy for individuals with moderate to severe OSA who are already on CPAP. The study provides evidence for inferiority of the Provent nasal device compared with CPAP and for the ineffectiveness of nasal dilators compared with a placebo device.

Berry et al. (2011) conducted a multicenter RCT that investigated the efficacy of the Provent nasal device, a nasal expiratory positive airway pressure (EPAP) device for treating OSA. Overall, 250 participants with mild to severe OSA were randomized to treatment with EPAP (n = 127) or a similar sham device (n = 123) for 3 months. A total of 229 completed week 1 sleep studies (119 EPAP; 110 sham). This group was the intention-to-treat (ITT) group. Of them, 173 had an AHI of > 5/hour on the device-off night and comprised the modified ITT group (92 EPAP; 81 sham). Overall, 195 participants in the ITT group (100 EPAP; 95 sham) and 144 participants in the modified ITT group (77 EPAP; 67 sham) completed the 3-month study. All participants underwent a baseline clinic evaluation that included the ESS. Polysomnography (PSG) was performed on two nonconsecutive nights (random order: device on, device off) at week 1 and after 3 months of treatment. At week 1, the EPAP device significantly decreased the AHI compared with device-off nights, and the difference was significantly greater than with the sham device (52.7% vs 7.3%; ITT analysis). At 3 months, 51% of the EPAP device users had a 50% or greater reduction in the AHI on device-on compared with device-off nights. The authors concluded that nasal EPAP significantly reduced the AHI and improved subjective daytime sleepiness compared with the sham treatment in participants with mild to severe OSA, with excellent adherence. This study is limited by a short follow-up, loss to follow-up, a lack of comparison with established treatment approaches, participant-reported adherence, a large number of exclusion criteria, and a modified ITT group. A potential for bias exists due to manufacturer sponsorship of the study.

Kryger et al. (2011) conducted a 13-center extension study of the 3-month Berry et al. trial. This study was designed to evaluate the long-term effectiveness of the Provent nasal device in participants who had responded in the initial study. Overall, 41 participants in the EPAP arm who met adherence and efficacy criteria continued therapy and returned for PSG after 12 months of treatment. From the analyzable participant cohort (n = 34), results from the 12-month PSG were compared against their baseline results. The median AHI was reduced from 15.7 to 4.7 events/hour (week 1 device off vs month 12 device on). The decrease in the AHI (median) was 71.3%. The ESS decreased from 11.1 ±4.2 to 6.0 ±3.2. The median percentage of reported nights used (entire night) was 89.3%. The authors reported that long-term adherence to EPAP was excellent in those who had a positive clinical response at month 3 of the Berry et al. trial. As with the original trial, this study is limited by participant-reported adherence and a large number of exclusion criteria. Additionally, analyses that are limited to responders are inherently biased to assess the impact of an intervention objectively. Furthermore, a potential for bias exists due to manufacturer sponsorship of the study.

Walsh et al. (2011) evaluated the tolerability and short-term efficacy of and adherence to the Provent nasal device, an EPAP nasal device, in 59 individuals with OSA who refused CPAP or used CPAP less than 3 hours per night. After demonstrating tolerability of the EPAP device during approximately 1 week of home use, 47 individuals (80%) underwent a baseline polysomnogram (PSG1). Overall, 43 individuals met the AHI entry criteria and underwent PSG2 within 10 days of PSG1. In total, 24 individuals (56%) met the prespecified efficacy criteria and underwent PSG3 after 5 weeks of EPAP treatment. Compared with PSG1, the mean AHI was significantly lower at both PSG2 and PSG3. For most individuals, the AHI at PSG3 was similar to the AHI at PSG2. Device use was reported for an average of 92% of all sleep hours. The authors concluded that improvements in AHI and ESS scores, combined with the high degree of treatment adherence observed, suggest that the EPAP device tested may become a useful therapeutic option for OSA. Limitations of the study include a lack of randomization and a control, small sample size, and short-term follow-up. A potential for bias exists due to manufacturer sponsorship of the study.

Removable Oral Appliances for Treating Central Sleep Apnea

Central sleep apnea (CSA) is the result of an impaired neurological function, and removable oral appliance devices are designed to manage physical obstructions. No relevant evidence has been identified to support the use of oral appliances for CSA.

Prefabricated Oral Appliances/Devices

The evidence for a prefabricated oral appliance or device is limited; there is a paucity of evidence that demonstrates the safety or efficacy of these devices for treating OSA. Furthermore, no evidence-based practice guidelines recommend prefabricated devices.

In an RCT, Johal and associates (2017) compare the effectiveness of ready-made vs custom-made mandibular repositioning devices (MRDs) in the management of mild to moderate OSA. Overall, 35 participants were randomized to

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receive either the ready-made or custom-made MRD. The primary outcome was measurement of the AHI, which was measured by an overnight home sleep study. The study demonstrated that custom-made MRDs had a significant impact in the treatment of OSA compared with the ready-made devices. The participants overwhelmingly found the ready-made appliance difficult to tolerate due to the limitation in the device design and inability to address individual needs. Limitations include a small number of participants and withdrawal of almost 30% of the participants after the 3-month treatment interval.

Nonsurgical Electrical Muscular Training

The evidence for nonsurgical electrical muscular stimulation is limited; there is little quality evidence to demonstrate the safety or efficacy for the treatment of OSA. Future studies are warranted, which should include comparison groups and test for safety, efficacy, and long-term outcomes.

The eXciteOSA device is a noninvasive, intraoral electrical muscle stimulation device for the treatment of mild OSA and snoring. The device works by delivering electrical muscle stimulation through a mouthpiece that sits around the tongue. The system consists of a mouthpiece, rechargeable control unit, and mobile app that allows the individual to control and track therapy. The suggested use for the device is 20 minutes each day during a wakeful state for 6 weeks and then once per week thereafter. A Hayes (2022) report, which was updated in 2024, identified three single-arm studies of poor or very-poor quality and suggests that there is no clear support for using eXciteOSA for the treatment of primary snoring or mild OSA.

Moffa et al. (2023) conducted a systematic review to evaluate the efficacy of noninvasive electric stimulation devices for the treatment of primary snoring and OSA. The review included literature that was published through September 2021 and that reported the use of an intraoral device that performs an awake neuromuscular electric stimulation of the tongue muscles. Four studies met the inclusion criteria, with two devices that were included in the review: Apone-Stim 400 Muscle Stimulator and eXciteOSA. Based on the review, the authors noted that the noninvasive electric stimulation devices improved snoring by 50%. Additionally, two studies showed a significant AHI improvement in mild OSA. The authors suggested that intraoral, noninvasive electrical stimulation devices can be a valid option for snoring. Limitations include the lack of comparison to other treatment approaches or sham as well as analyses that were focused on pre-post comparisons. (Baptista et al., 2021, and Kotecha et al., 2021, previously cited in this policy, are included in this systematic review.)

An ECRI (2022) Clinical Evidence Assessment identified very-low-quality evidence from three pre-post studies, which suggests that eXciteOSA may improve symptoms in some individuals with mild OSA but does not draw any supportable conclusions. There are no published studies that provide a comparative analysis between eXciteOSA and other OSA treatments in individuals with mild OSA. Limitations include a high risk of bias, lack of blinding, and lack of long-term efficacy. The authors concluded that the evidence is inconclusive. Further RCTs, with long-term outcomes, are needed to address these gaps.

Mandibular Vertical Repositioning Devices (e.g., Slow Wave)

Extensive research of the medical literature was conducted, and no quality evidence was identified to support the efficacy and safety of MRDs that open the jaw vertically for OSA.

Morning Repositioning Devices

No published studies that address the use of morning repositioning devices were identified; therefore, their effect on health outcomes is unknown.

Epigenetic Appliances

Epigenetic appliances are intraoral devices that are similar to an orthodontic retainer in appearance. The premise is that when the appliance is worn overnight, pressure is applied to the jaw, resulting in expansion due to the stimulation of osteoblasts and osteoclasts. They are purported to help a wide variety of conditions, including but not limited to temporomandibular joint disorders, sleep apnea, and chronic headaches. No quality evidence is available to support the efficacy of this therapy for OSA.

Advanced Lightwire Functional Appliances

The Advanced Lightwire Functional appliance is a cranial osteopathy-based orthodontic system that uses a custom appliance made of light, flexible wire. Proponents of this device state that it applies subtle forces that closely mimic the natural growth and development process and that it can widen and/or reposition the jaws. No quality evidence is available to support the efficacy of this therapy for OSA.

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Clinical Practice Guidelines

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

It is the recommendation of the AAO-HNS that patients presenting with symptoms of OSA require a face-to-face evaluation conducted by a qualified physician trained in otolaryngology-head and neck surgery or sleep medicine (one who maintains certification from the American Board of Sleep Medicine or one of the sponsoring sleep medicine boards of the American Board of Medical Specialties, including the American Board of Otolaryngology) (AAO-HNS Position Statement: Use of Oral Appliances for the Treatment of Obstructive Sleep Apnea, 2014; revised 2019).

An AAO-HNS position statement for the treatment of OSA recommends an oral appliance as a first-line treatment for patients with mild to moderate OSA (AAO-HNS Position Statement: Treatment of Obstructive Sleep Apnea, 2010; revised 2021).

American Academy of Sleep Medicine (AASM)

The AASM Clinical Practice Guideline on the treatment of OSA with positive airway pressure (PAP) recommends CPAP or automatic PAP for ongoing treatment of OSA in adults (Patil et al., 2019).

The AASM makes the following recommendations regarding OAT (Ramar et al., 2015):

- When OAT is prescribed by a sleep physician for an adult patient with OSA, the guidelines suggest that a qualified dentist use a custom, titratable appliance over noncustom oral devices. Strength of recommendation: guideline. Quality of evidence: low. Benefits clearly outweigh harms.
- Sleep physicians should consider prescription of oral appliances, rather than no treatment, for adult patients with OSA who are intolerant of CPAP therapy or who prefer alternate therapy. Strength of recommendation: standard. Quality of evidence: moderate. Benefits clearly outweigh harms.
- Qualified dentists should provide oversight, rather than no follow-up, of OAT in adult patients with OSA to survey for dental-related side effects or occlusal changes and reduce their incidence. Strength of recommendation: guideline. Quality of evidence: low. Benefits clearly outweigh harms.
- Sleep physicians should conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients who are fitted with oral appliances. Strength of recommendation: guideline. Quality of evidence: low. Benefits clearly outweigh harms.
- Sleep physicians and qualified dentists should instruct adult patients who are treated with oral appliances for OSA to return for periodic office visits, as opposed to no follow-up, with a qualified dentist and a sleep physician. Strength of recommendation: guideline. Quality of evidence: low. Benefits clearly outweigh harms.

American Academy of Sleep Medicine (AASM)/American Academy of Dental Sleep Medicine (AADSM)

In a 2015 joint guideline for the treatment of OSA and snoring with oral appliances, the AASM and AADSM make the following recommendations (Ramar et al., 2017):

- Sleep physicians should prescribe oral appliances rather than no therapy for treating snoring in the absence of OSA
- For patients who are prescribed an oral appliance for OSA, a dentist should construct an adjustable, titratable appliance over a prefabricated device and instruct patients to return for periodic office visits
- Qualified dentists should provide oversight to assess for dental-related side effects with OAT
- Sleep physicians should conduct follow-up sleep testing to confirm or improve treatment efficacy

American Association of Oral and Maxillofacial Surgeons (AAOMS)

In a position paper on the evaluation and management of OSA, the AAOMS reveals that oral appliances have been shown to be effective in patients with mild to moderate OSA. Custom-made oral appliances may be indicated for use in patients with severe OSA who have experienced failure of CPAP treatment. These custom-made appliances should be fitted by qualified dental personnel (AAOMS, 2013). The paper does not address prefabricated oral devices.

American College of Physicians (ACP)

The ACP developed a clinical practice guideline on the management of OSA in adults (Qaseem et al., 2013). The guideline makes the following recommendations:

- All overweight and obese patients who are diagnosed with OSA should be encouraged to lose weight (grade: strong recommendation; low-quality evidence)
- CPAP treatment is recommended as the initial therapy for patients who are diagnosed with OSA (grade: strong recommendation; moderate-quality evidence)

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European Respiratory Society (ERS)

An ERS guideline (Randerath et al., 2021) on non-CPAP therapies for patients with OSA makes the following recommendations for adult patients with OSA:

- Based on very-low-quality evidence, for adult patients with OSA, the panel suggests that CPAP be used vs a custom-made dual-block mandibular advancement device
- Based on low-quality evidence, the panel suggests that myofunctional therapy can be used as a standard/regular treatment for OSA compared with no therapy at all but only for specific patients who are seeking alternative treatments and are reluctant to undertake surgical or mechanical strategies
- Based on low-quality evidence, the panel suggests using CPAP instead of myofunctional therapy in adult patients with OSA
- Based on a very low certainty of evidence, the panel suggests either positional therapy (using vibratory devices) or CPAP in adult patients with mild or moderate position-dependent OSA, as defined by a supine AHI at least twice as high as the nonsupine AHI and no relevant nonsupine AHI (< 15 events/hour)
- Based on a very low certainty of evidence, for patients with mild positional OSA, the panel suggests that either vibrational positional therapy or a custom-made dual-block mandibular advancement device be used

Surgical Treatment

In the TEAMUP (Tonsillectomy and Modified Uvulopalatopharyngoplasty) RCT in 90 participants with moderate to severe OSA, Sundman et al. (2022) investigated whether modified uvulopalatopharyngoplasty (UPPP) was more effective than a tonsillectomy. Participants were aged 30 to 65 years, had an AHI score of > 15 events/hour, had a tonsil size of 2, 3, and 4 on the Friedman scale, and had experienced failure of nonsurgical treatment. All participants were blinded, and stratified randomization was performed by means of two groups categorized by tonsil size: participants in group A had medium-size tonsils (Friedman size 2) and group B had large-size tonsils (Friedman size 3 and 4). Participants were not told which surgical procedure (modified UPPP vs tonsillectomy) they had received, neither after surgery nor during follow-up. Each participant underwent two PSG procedures: one prior to the procedure and the other 6 months after. The ESS questionnaire was completed twice during the trial: once during preoperative PSG and the other after the second postoperative PSG. The primary outcome was a change in the AHI score from baseline to 6 months post operation. The authors found that the AHI score decreased from 51 to 28 events/hour in the modified UPPP group and 56.9 to 24.7 events/hour in the tonsillectomy group. The ESS score also demonstrated positive results, with 78 participants responding to the questionnaire; scores decreased from a baseline score of 9.1 to 5.8 at 6 months in the modified UPPP group and 11.4 to 7.2 in the tonsillectomy group. The authors concluded that the study did not validate that modified UPPP was any more effective than tonsillectomy; in fact, there may have been slight bias for the tonsillectomy procedure. Future studies that include long-term outcomes are warranted. Limitations include a small sample size, inability to generalize the results to the overall population, and lack of long-term outcomes.

In a case series of 65 individuals, Sundman et al. (2021) investigated the long-term effectiveness of modified UPPP in those with OSA. Eight years after receiving UPPP for OSA, 65 individuals were offered a reevaluation of their condition with PSG and the ESS; results were compared with their 2-year follow-up results. The authors found that modified UPPP was effective as a long-term solution for the treatment of OSA, although the AHI decreased over time. Limitations include a small sample size, lack of comparison groups, and lack of female individuals, making generalization difficult.

A systematic review and meta-analysis that was performed by Zhou et al. (2021) evaluated the efficacy of eight different variations of maxillomandibular advancement (MMA) surgical treatment for individuals with OSA. Eight articles, including 227 individuals, were included. All studies included AHI results, but only five studies reported SpO2, and six studies reported postoperative ESS scores. The authors found that MMA combined with UPPP with uvula preservation had the highest efficacy rate compared with any of the other MMA combinations. Limitations include the small number of articles, in addition to the small number of individuals in each of the studies (due to the newer MMA methods that have been developed in recent years), and a lack of indicators used in each of the studies for OSA analysis (three factors is not considered adequate to sufficiently evaluate OSA); therefore, the analysis was not satisfactory.

The AASM commissioned a task force of sleep medicine experts to conduct a systematic review and meta-analysis in individuals with a diagnosis of OSA who were referred for surgical intervention (Kent et al., 2021). Overall, 274 articles, including RCTs and observational studies, met the criteria and were included in the analysis. The task force concentrated on four topics that pertained to the use of surgery to treat adult OSA: (1) surgical treatment of individuals who were intolerant or unaccepting of PAP; (2) surgical treatment of individuals with obesity with bariatric surgery; (3) surgical treatment of individuals to facilitate PAP use; and (4) surgical treatment as an initial therapy in individuals with a major upper airway anatomical abnormality. For surgical treatment of those intolerant or unaccepting of PAP, a total of four RCTs and 239 observational studies were analyzed; individuals with oropharyngeal obstruction were included. Two RCTs and 15 observational studies were found that addressed surgical treatment as an initial therapy in individuals with a major

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upper airway anatomical abnormality. The individuals in the two RCTs were mostly male, with a mean body mass index (BMI) of < 30 kg/m^2 and diagnosis of moderate to severe OSA; they also had tonsillar hypertrophy, with velopharyngeal obstruction, and were intolerant of or refused CPAP therapy. Overall, the task force determined that the overall quality of evidence was low for the use of surgical treatments as an initial therapy for individuals who are intolerant or unaccepting of CPAP due to the risk of bias that is associated with observational studies and the imprecision in the RCTs. Several areas were identified that warrant further investigation, but it was demonstrated that individuals with major upper airway obstruction benefit from surgery and that appropriate referral for surgical consultation is vital. Limitations include the variability in procedure choice and technique, nonstandardized reporting of outcomes, small and heterogeneous study populations, selection bias, and lack of blinding. The authors identified that further studies are required to better evaluate individual preference for PAP vs surgery as a first-line therapy. Additional comparative studies that compare surgery with medical therapies for OSA and include long-term assessment of the surgical interventions are needed.

MacKay et al. (2020) assessed the efficacy of a multilevel surgery (modified UPPP and minimally invasive tongue volume reduction) as a treatment for participants with OSA compared with that of conventional treatment. The multicenter RCT included participants who were 18 to 70 years of age and had moderate or severe OSA that was defined as an AHI of 15 to 30 and > 30 events per hour of sleep. Additional inclusion criteria were a BMI of < 38 kg/m^2, an ESS of > 8, failure with medically supervised attempts to use CPAP, and when appropriate, failure with or refusal of a mandibular advancement device. The primary outcome measures were the AHI and ESS at 6 months. Overall, 102 participants were included in the study, of whom 51 were randomized to the intervention arm and 51 to the control arm. In the intervention group, prior to the procedure, the mean AHI was 47.9, and the ESS was 12.4; at 6 months post procedure, the AHI was 20.8, and the ESS was 5.3. In the medical management group, at baseline, the mean AHI was 45.3, and the ESS was 11.1; at 6 months, the mean AHI was 34.5, and the ESS was 10.5. The authors concluded that multilevel upper airway surgery resulted in significant reductions in the frequency of sleep apnea and daytime sleepiness in participants with moderate to severe OSA for which prior conventional treatment had failed. Limitations include the establishment of long-term effectiveness, reduced generalizability due to exclusion criteria and underrepresentation of women, and inability to mask the participants, which may have influenced self-reported sleepiness.

John et al. (2018) conducted a systematic review with meta-analysis on the effectiveness of MMA as a successful treatment modality in improving airway patency in individuals with OSA. Overall, 462 individuals from 20 studies were included for the analysis. The authors found that substantial improvements were seen following surgical intervention in outcome measures for the AHI, the Respiratory Disturbance Index (RDI), the ESS, and lowest oxygen saturation and concluded that MMA is a successful treatment option for OSA. Limitations include selection bias for article identification; inclusion of only one RCT; the lack of a parallel comparison group that underwent a different treatment; and the fact that few studies reported MMA as an isolated primary procedure.

In a 2017 overview of 11 systematic reviews, Tan et al. assessed the evidence for pharyngeal airway dimension changes following mandibular advancement surgery with or without concomitant maxillary surgery. Data from reviews that reported respiratory parameter changes were also included. Studies of specific target groups, such as edentulous and morbidly obese individuals and those with cleft lip and palate or syndromic or distraction osteogenesis, were excluded. Two systematic reviews reported on the effects of various orthognathic surgeries on the pharyngeal airway, and eight focused on MMA and other surgical treatments that were related specifically to OSA. Additionally, two were focused on pharyngeal airway analyses; four reviews analyzed changes in respiratory parameters; and the remainder evaluated both. The results showed a relatively high success rate with MMA and a significant reduction in the AHI for the treatment of OSA, as shown by increased linear, cross-sectional, and volumetric measurements. For mandibular advancement alone, five studies reported significantly enlarged pharyngeal airway dimensions. This result was proved unstable during a long-term follow-up of 12 years, with lower parts of the pharyngeal airways relapsing to preoperative values. This review is limited by the quality of the systematic reviews that were reviewed, and the authors recommended that it be read with caution.

Zaghi et al. (2016) conducted a meta-analysis on the success and effectiveness of MMA for OSA. Overall, 45 articles were included for review, which included 518 individuals. The study inclusion criteria included adults 18 years of age or older who underwent MMA, along with preoperative and postoperative outcomes for the AHI and/or RDI. In addition, the following individual data were extracted from each article: prior OSA surgery, BMI, SpO2, ESS score, posterior airway space, length of maxilla advancement, length of mandible advancement, and Sella-Nasion points A and B angles. The main outcome measure was the change in AHI or RDI score. The authors found that 90% of individuals experienced improvements in their AHI and RDI scores following surgical intervention. The authors concluded that MMA is a highly effective treatment for OSA, which was proved by substantial improvements in both the AHI and RDI. Limitations include studies that included only reported data for the individuals, which introduced selection bias. These studies also had an absence of long-term follow-up (i.e., 10-15 years post-surgical treatment) and, in general, a lack of a comparison group of individuals who underwent a different treatment approach.

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Sommer et al. (2016) evaluated the effectiveness of tonsillectomy with UPPP in adults with OSA in a two-center RCT. The trial was prospective and included participants between the ages of 18 and 65 years who had OSA confirmed by PSG; an AHI of > 15; tonsillar hypertrophy with velopharyngeal obstruction that was confirmed by physical examination; and rejection of or poor adherence to CPAP. The primary outcome that was measured was the AHI, and secondary outcomes that were measured included the ESS, snoring, and oxygenation. Overall, 19 participants were in the control group, and 23 were in the treatment group. The results that were reported included 18 participants in the treatment group and 16 in the control group. The baseline AHI in the control group was 35.7 ±19.4/hour compared with 33.7 ±14.6/hour in the treatment group. After 3 months, participants in the treatment group had an AHI of 15.4 ±14.1/hour compared with 28.6 ±19.4/hour in the control group. Results also indicated an improvement in the ESS and snoring. Limitations of the study include loss to follow-up in participants in both the treatment and control groups as well as a short follow-up period, which prevented the evaluation of long-term efficacy.

Hypoglossal Nerve Stimulation

Heiser et al. (2023) compared hypoglossal nerve stimulation (HNS) therapy with PAP treatment, with outcome parameters of sleepiness, the AHI, and effectiveness. Overall, 126 participants who were diagnosed with OSA were included for analysis and separated into two cohorts; 63 were treated with PAP, and the other 63 had been treated with HNS. PAP was the first line of treatment; then, if failure or participant intolerance occurred, HNS was the second line of treatment. The ESS was used to report sleepiness, which was assessed at baseline and again at 12 months; the baseline ESS was higher in the HNS cohort than in the PAP group. The primary end point for the study was the assessment of the effect of the two treatments on sleepiness. At the 12-month follow-up, the mean AHI was 6.6 ±8.0 in the PAP group and 8.1 ±6.3 in the HNS cohort, which the authors felt was a significant reduction for both. Clinically, it was shown that both groups experienced improvements in sleepiness, but the study demonstrated that HNS therapy was superior in relation to improving daytime sleepiness. Data for HNS therapy were 7.5 ±4.7 vs 10.8 ±5.6 for PAP treatment; the authors felt that the 3.3-point difference was not statistically significant. Among the participants who were treated with PAP, it was identified that CPAP was the most used (68%), followed by automated PAP (19%), and finally bilevel PAP (13%). Limitations include the lack of comparison groups and long-term follow-up.

In a Clinical Evidence Assessment by ECRI (2021), evidence from one systematic review and six nonrandomized comparison studies suggests that the Inspire Upper Airway Stimulation system may outperform other surgeries in improving sleep and reducing OSA symptoms. The authors noted that the evidence is somewhat favorable, with the following limitations in the body of evidence: short follow-up, small sample sizes, a retrospective design, and attrition of individuals. Future controlled studies that provide long-term data are needed to validate the benefits with Inspire and compare Inspire with CPAP therapy.

A Hayes report concluded that the overall quality of the evidence evaluating HNS for treating OSA is very low. However, evidence suggests that the intervention is relatively safe, may reduce the severity of OSA, and may improve patient-reported outcome measures (excessive daytime sleepiness, function, and QOL) in individuals with OSA who have experienced failure of or are intolerant of CPAP therapy. Stimulation of the hypoglossal nerve may provide a treatment option for individuals with moderate to severe OSA for whom CPAP has failed to provide relief, but the procedure may carry risks of complications and postimplant surgical procedures. Additional good-quality, comparative studies, with larger sample sizes, are needed to define the population of individuals that is most likely to respond to this therapy option (Hayes, 2018; updated 2022).

Costantino et al. (2020) conducted a meta-analysis of nine case series, which evaluated HNS for the treatment of moderate to severe OSA and compared before and after treatment. Inspire was implanted in 68% of individuals, with a success rate of 75% at 5 years. In contrast, 18% of individuals were treated with the aura6000 system, with a success rate of 35%. All primary clinical outcomes such as the AHI, ODI, and ESS showed improvement at the 12- and 60-month assessments. Several minor adverse effects were experienced by several individuals, but all were nonserious and resolved. While the authors found that HNS is an effective and safe surgical procedure for individuals with OSA, a subgroup analysis demonstrated that there are not enough data to compare clinical outcomes with those with different stimulation systems. The Stimulation Therapy for Apnea Reduction (STAR) trial (see Strollo and Woodson below) was the only study to include long-term data, which is a limitation of this analysis; other limitations include the lack of comparison groups and RCTs.

The STAR trial (Strollo et al., 2014, included in the Hayes and ECRI reports, and Costantino et al., 2020, above) evaluated the clinical safety and effectiveness of upper airway stimulation at 12 months for the treatment of moderate to severe OSA. Using a multicenter, prospective case series design, an upper airway stimulation device was surgically implanted in participants with OSA who had difficulty either accepting or adhering to CPAP therapy. The primary outcome measures were the AHI (the number of apnea or hypopnea events per hour, with a score of ≥ 15 indicating moderate to severe apnea) and ODI (the number of times per hour of sleep that the blood oxygen level drops by ≥ 4 percentage points

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from baseline). The secondary outcome measures were the ESS, Functional Outcomes of Sleep Questionnaire, and percentage of sleep time with an oxygen saturation of less than 90%. The study included 126 participants; 83% were men. The mean age was 54.5 years, and the mean BMI was 28.4 kg/m^2. The median AHI score at 12 months decreased by 68% from 29.3 events per hour to 9.0 events per hour; the ODI score decreased by 70% from 25.4 events per hour to 7.4 events per hour. Secondary outcome measures showed a reduction in the effects of sleep apnea and improved QOL. In the randomized phase, the mean AHI score did not differ significantly from the 12-month score in the nonrandomized phase in the 23 participants in the therapy maintenance group (8.9 and 7.2 events per hour, respectively); the AHI score was significantly higher (indicating more severe apnea) in the 23 participants in the therapy withdrawal group (25.8 vs 7.6 events per hour). The ODI results followed a similar pattern. The rate of procedure-related serious adverse events was less than 2%. The authors concluded that upper airway stimulation led to significant improvements in objective and subjective measurements of the severity of OSA. The lack of a control group limits the validity of the results of this study. This study was funded by Inspire Medical Systems, Inc. Follow-up studies in the same participant population at 18 and 36 months indicate that the treatment effects are maintained over time. Limitations are the same as those of the original study (Strollo et al., 2015; Woodson et al., 2016).

In a subgroup analysis of the STAR trial, Woodson et al. (2014, included in the Hayes and ECRI reports, and Costantino et al., 2020, above) assessed the efficacy and durability of upper airway stimulation via the hypoglossal nerve on OSA severity, including objective and subjective clinical outcome measures. The study included a consecutive cohort of 46 responders at 12 months from a prospective, phase 3 trial in 126 implanted participants. Participants were randomized to either the therapy maintenance (ON) group or therapy withdrawal (OFF) group for a minimum of 1 week. The short-term withdrawal effect as well as durability at 18 months of primary (the AHI and ODI) and secondary outcomes (the Arousal Index, oxygen desaturation metrics, the ESS, the Functional Outcomes of Sleep Questionnaire, snoring, and BP) were assessed. Both the therapy withdrawal group and maintenance group had significant improvements in outcomes at 12 months compared with study baseline. In the randomized assessment, the therapy withdrawal group returned to baseline, and the therapy maintenance group had no change. At 18 months with therapy on in both groups, all objective respiratory and subjective outcome measures showed sustained improvements similar to those observed at 12 months. The authors concluded that withdrawal of therapeutic upper airway stimulation resulted in worsening of both objective and subjective measures of sleep and breathing, which when resumed, resulted in a sustained effect at 18 months. The authors stated that reduction of OSA severity and improvement of QOL were attributed directly to the effects of the electrical stimulation of the hypoglossal nerve**.** The author-reported limitations of this study include the selection bias of only including responders to upper airway stimulation device therapy and lack of participant and investigator blinding. This study was funded by Inspire Medical Systems, Inc.

Down Syndrome

Rodriguez Lara et al. (2024) conducted a systematic review of the advances in the use of HNS in adolescents with Down syndrome and persistent OSA after adenotonsillectomy and a trial of CPAP therapy. Ten studies that investigated the use of HNS in children, comprising 121 individuals, were included: three prospective clinical trials, one cross-sectional study, four case series, and two case reports. Outcomes included changes in the AHI, QOL, and sleep measures using the Obstructive Sleep Apnea-18 (OSA-18) survey, which is a validated, disease-specific survey that includes questions in five domains (sleep disorders, physical distress, emotional distress, diurnal problems, and caretaker occupation). The results showed improvement in the AHI across all studies and ranged from 48% to 93%, with the effectiveness largely based on one prospective clinical trial in 42 individuals. In general, the QOL and ESS questionnaires also showed significant improvement, even in individuals with posttherapy AHI events greater than 5 events per hour. These results continued through 12 months post-surgery, with one case series showing sustained improvement up to 48 months. The authors concluded that HNS not only improves objective sleep parameters but also has a positive impact on the overall well-being, functional aspects, and cognitive abilities of the pediatric population with Down syndrome and persistent OSA. These findings cannot be extrapolated to pediatric individuals without Down syndrome, and further research in that population is required.

In a 2023 evidence analysis on the Inspire Upper Airway Stimulation System for treating OSA in children with OSA, it was concluded that there are too few data available to assess the efficacy in children with Down syndrome. Efficacy and safety cannot be determined by the available evidence, which features no control groups, no randomization, and a lack of longer-term follow-up. An ongoing clinical trial may address these evidence gaps.

In a systematic review and meta-analysis by Liu et al. (2022), the authors evaluated the efficacy of HNS in adolescents with Down syndrome and OSA. A literature search was performed using the PubMed, Web of Science, Embase, and Scopus databases. A total of nine studies (three cases series, three prospective studies, and three case reports) were found and included 106 adolescents, who were aged 10 to 21 years. All the adolescents included in this review were unable to tolerate CPAP after trial usage, and after receiving HNS therapy, they all had a decrease in AHI score. Three studies reported adverse events such as tongue or mouth pain, rash, inflammation, insomnia, pneumothorax, and

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swallowing or speech-related problems. The authors concluded that HNS was found to be an effective treatment for OSA in adolescents with Down syndrome and was considered a better option than CPAP. Limitations include small sample sizes and case reports, a lack of control groups, and a lack of long-term outcomes; future large-scale, prospective RCTs are required.

Yu et al. (2022; included in the Liu et al., 2022, and Rodriguez Lara et al., 2024, systematic reviews and the ECRI 2023 Evidence Analysis) evaluated the safety and effectiveness of upper airway stimulation in adolescent participants with Down syndrome and severe OSA. This phase 1 prospective study included 42 adolescents with Down syndrome (at least 10 years of age or < 22 years of age) with severe OSA. All participants underwent PSG prior to enrollment if they did not have one in the previous 6 months and then underwent a drug-induced sleep endoscopy under sedation with propofol and/or dexmedetomidine; they were excluded if they had circumferential palatal collapse. Eligible participants received an HNS implant, which was activated in the clinic 1 month after placement. Follow-up PSG was obtained at 2, 6, and 12 months. The most common adverse event was tongue or oral discomfort or pain, which occurred in five participants and was temporary. Some participants exacerbated complications (such as site infection and postoperative pain) by picking at the incision site, which resulted in hospital readmission, but no life-threatening events were found. Responders were identified as having at least a 50% postoperative decrease in the AHI, and 27 of the 41 participants achieved this; the mean percentage change in the AHI was -51.2%. At 12 months, the mean change in the AHI was a decrease of 12.9 events/hour. The authors concluded that this cohort of participants had a high therapy response rate, along with improvement in their QOL, after the implant of an upper airway stimulation device. Limitations include a small sample size, lack of a control group, and lack of long-term outcomes.

In a case series of 20 adolescents with Down syndrome and severe OSA, Caloway et al. (2020) evaluated the safety and efficacy of HNS. The individuals were aged 10 to 21 years and unable to tolerate CPAP or were dependent on tracheostomy at night. All individuals underwent PSG prior to enrollment if they did not have one in the previous 6 months and then underwent a drug-induced sleep endoscopy to exclude circumferential collapse. Individuals received an HNS implant, which was then activated 1 month after placement. Caregivers completed the OSA-18 questionnaire at baseline and 2 months following device implantation for QOL assessment. The results indicated that all individuals had significant improvement in their QOL, as demonstrated by a change in the OSA-18 score of 1.15. The authors found that the median percent reduction in the AHI was 85%. Two adverse events occurred, which required revision surgery, and both resolved. It was concluded that HNS is safe, effective, and tolerable in children with Down syndrome and OSA. Limitations include a small sample size, no comparison groups, and a lack of long-term outcomes; future studies are required.

Implantable Neurostimulation Devices for the Treatment of Central Sleep Apnea

The remedē System (ZOLL® Medical Corporation) is an implantable phrenic nerve stimulation (PNS) device that is intended to treat adults with moderate to severe CSA (Hayes, 2023). The current evidence for implantable neurostimulation devices for the treatment of CSA is insufficient, thus requiring additional research for its safety and efficacy.

A 2024 Hayes Technology Assessment, which was updated in 2025, concluded that there is a very-low-quality body of evidence evaluating the use of PNS with the remedē System in adults with CSA. The evidence is insufficient to draw conclusions about the efficacy and safety of PNS due to an evidence base that consists of three fair- to poor-quality studies, with small sample sizes; two of the three studies have limited follow-up. The clinical impact in individuals with CSA, especially those with heart failure, remains uncertain. While results suggest a statistically significant reduction in AHI events, average AHI scores did not achieve normal to mild disease severity. According to the authors of the report, studies that compare the efficacy, safety, individuals' acceptance, and cost-effectiveness of PNS with other noninvasive, available therapies for CSA are needed. In addition, studies with longitudinal data are needed to assess the effect of PNS on CSA-related morbidity and mortality. There were no 2025 updates that changed this conclusion.

In a meta-analysis, Wang et al. (2023) evaluated the efficacy of PNS in individuals with CSA. A literature search was done using the PubMed, Embase, Cochrane Central Register of Controlled Trials, Scopus, and Web of Science databases. The search returned three RCTs and seven observational studies, which totaled 580 individuals. Overall, the authors found that the scores for the AHI, Central-Apnea Index (CAI), and Arousal Index were notably reduced following PNS, but no remarkable differences were observed in either the ESS or total sleep time with oxygen saturation below 90%. While PNS appears to have a positive impact in individuals with CSA, the authors suggested that additional RCTs are needed to assess long-term outcomes with the procedure; limitations include a low number of RCTs that were available for analysis.

An updated 2021 ECRI Clinical Evidence Assessment on the remedē System focused on the safety and efficacy in treating individuals with moderate to severe CSA. The available evidence suggests that transvenous phrenic nerve stimulation (TPNS) with remedē improves sleep quality and QOL in individuals with moderate to severe CSA for up to 5 years. The literature consisted of one systematic review, three publications of one RCT, and one pre-/posttreatment

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study. The systematic review consisted of five studies that compared the severity of apnea in individuals with active remedē implants against controls. The RCT compared a change in apnea severity by collecting AHI scores during a 5-year period, along with conducting global assessments in the individuals and assessing daytime sleepiness in those with active remedē implants against controls who received inactive remedē implants; however, after 6 months, the study was no longer considered an RCT due to the permission of individuals in the control arm to cross over to active stimulation. The pre-/posttreatment study reported apnea severity, daytime sleepiness, QOL, deaths, and adverse events in 57 individuals with moderate to severe CSA who were treated with the remedē System. Limitations include a high risk of bias in the systematic review due to a small sample size, a single-center focus, and subjective outcomes in the unblinded individuals; a risk of bias in the RCT due to reporting of subjective measures; and a small sample size, along with a lack of controls in the pre-/posttreatment study. Additional studies that compare remedē with alternative treatment options and have long-term outcomes are needed to assess and compare the system's safety and efficacy.

Potratz et al. (2021) conducted a prospective case series in 24 participants with heart failure and CSA that was diagnosed by PSG. They evaluated PSG (to determine hypoxemic burden), echocardiography, and a standardized 6-minute walk test prior to device implantation (baseline) and after 6 months. The results showed that the 6-minute walk distance was 369.5 ±163.5 m at baseline and significantly improved during follow-up (to 410 ±169.7 m). Hypoxemic burden, which was determined based on time with oxygen saturation of < 90%, improved from 81 ±55.8 minutes at baseline to 27.9 ±42.8 minutes during PNS therapy. The authors concluded that in addition to safely and effectively treating CSA, PNS is also associated with improved physical performance capacity and reduced hypoxemic burden in individuals with heart failure. However, the study is limited by the lack of a comparison group. Although the findings are promising, the clinical benefits with PNS therapy in this population need to be determined in a large RCT with robust and objective clinical end points, including mortality.

In a post approval study to the remedē System Pivotal Trial (Costanzo et al., 2016), Costanzo et al. (2021) collected clinical evidence that addressed long-term safety and efficacy through 5 years following the placement of the remedē implant, which supplied TPNS. Of the original 151 participants, 52 took part in the 5-year visit. Clinical data were collected for the AHI, the CAI, the Arousal Index, the ODI, and sleep architecture. The median ESS in participants at baseline was 9 and dropped to 6 by the 5-year visit, demonstrating a clinically meaningful reduction; the AHI and CAI showed similar results for improvement. Severe adverse effects were minimal and included one lead dislocation, two stimulation lead component failures, and one implant infection. The authors suggested that TPNS delivered with remedē is safe and effective, resulting in improved sleep for participants. Limitations include the lack of a control group and lack of data availability for a large proportion of initial participants, which could have led to an underestimation of severe adverse effects.

In a 2020 systematic review and meta-analysis, Voigt et al. compared the outcomes with therapies in individuals with CSA and heart failure with reduced ejection fraction. Overall, 19 randomized studies were identified that met the inclusion criteria of an AHI of ≥ 10, predominant CSA, and heart failure with reduced ejection fraction of ≤ 50%. Most trials examined adaptive servoventilation (eight studies) and CPAP (nine studies). The authors identified only one RCT for TPNS, described in detail below (Costanzo et al., 2016).

As a follow-up to the study discussed below (Costanzo et al., 2016), Costanzo et al. (2018, included in the Hayes report above) conducted an analysis in all 96 participants who were randomized in the manufacturer-sponsored remedē System Pivotal Trial. Effectiveness data from treatment and former control groups were pooled based on months since therapy activation. Changes from baseline to 6 and 12 months in sleep metrics, the ESS, patient global assessment health-related QOL, the Minnesota Living with Heart Failure Questionnaire, and echocardiographic parameters were reported. Heart failure hospitalization, cardiovascular death, and the composite of heart failure hospitalization or cardiovascular death within 6 months were reported by the original randomized group assignment for safety assessment. Sleep metrics and QOL improved from baseline to 6 and 12 months. At 12 months, Minnesota Living with Heart Failure Questionnaire scores changed by -6.8 ±20.0. The 6-month rate of heart failure hospitalization was 4.7% in treatment participants and 17.0% in control participants. Reported adverse events were as expected for a transvenous implantable system. The authors concluded that PNS reduces CSA severity in individuals with heart failure. In parallel, this CSA treatment was associated with benefits for heart failure QOL. These findings are limited by the lack of a comparison group that was undergoing a different treatment.

In a manufacturer-sponsored, prospective, multicenter, randomized clinical trial, Costanzo et al. (2016, included in the Hayes report above) sought to evaluate the safety and effectiveness of unilateral neurostimulation in participants with CSA. Participants were recruited from 31 hospital-based centers in Germany, Poland, and the US. Participants must have been medically stable for at least 30 days; had received appropriate guideline-recommended therapy; been aged at least 18 years; been expected to tolerate study procedures; and been willing and able to adhere to study requirements. Eligible participants with an AHI of at least 20 events per hour, tested by PSG, underwent device implantation and were randomly

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assigned by a computer-generated method to either stimulation (treatment) or no stimulation (control) for 6 months. The primary effectiveness end point in the ITT population was the comparison of the proportions of participants in the treatment vs control groups who achieved a 50% or greater AHI reduction from baseline to 6 months, measured by full-night PSG that was assessed by masked investigators in a core laboratory. The primary safety end point of 12-month freedom from serious adverse events related to the procedure, system, or therapy was evaluated in all participants. Overall, 151 eligible participants were randomly assigned to the treatment or control groups. In the analysis of the results, significantly more participants in the treatment group had an AHI reduction from baseline of 50% or greater at 6 months (51%) compared with the control group (11%; difference between groups, 41%; 95% CI, 25%-54%; $p < 0.0001$). In total, 138 of 151 participants had no serious related adverse events at 12 months. Seven cases of related serious adverse events occurred in the control group, and six cases were reported in the treatment group. Overall, 27 of 73 participants in the treatment group reported nonserious therapy-related discomfort that was resolved with simple system reprogramming in 26 participants but was unresolved in one. According to the authors, this study showed that transvenous neurostimulation can significantly reduce the severity of CSA and concluded that it may be a promising therapeutic approach. Further research is needed to determine the clinical relevance of these findings. One of the study limitations is that participants and physicians were aware of treatment assignment, which could have introduced biases. The lack of long-term follow-up and a relatively small sample size are other limitations of this study.

Lingual Suspension/Tongue Fixation

Lingual suspension is intended to keep the tongue from falling back over the airway during sleep. This procedure involves inserting a bone screw into the lower jaw. A cable is then threaded through the base of the tongue and anchored to the bone screw. It is usually performed in conjunction with other procedures. No studies on the long-term success of this procedure are available, and there is little quality clinical data to demonstrate its efficacy.

In a 2022 systematic review and meta-analysis, Calvo-Henriquez et al. reviewed the complication rate with minimally invasive base-of-tongue procedures for OSA in adults. The inclusion criteria were studies of adults who received isolated tongue base surgery as an isolated procedure, including lingual suspension, tongue base radiofrequency, submucosal minimally invasive lingual excision, transoral robotic surgery (TORS), and tongue base ablation to treat obstructive sleep apnea syndrome (OSAS) or snoring. Complications were classified as mild, moderate, or severe. A total of 20 studies, comprising 542 individuals, met the inclusion criteria. The results showed a mild complication rate of 4.65%, moderate complication rate of 6.42%, and severe complication rate of 1.77%, for an overall complication rate of 12.79%. One study showed a complication rate of 42.42% for tongue base ablation with coblator, with TORS showing 35.78%. Regarding severe complications, tongue base ablation showed the highest incidence of 15.15%, followed by TORS. The most commonly reported complication overall was infection, followed by transient swallowing disorder. Suture extrusion or fracture was the most frequently reported complication, with an incidence of 9.30%. The authors concluded that minimally invasive base-of-tongue procedures may present a wide spectrum of complication rates, and the heterogeneity (differences in the selection of individuals, surgical technique, and evaluation methodology) of the included studies prevents strong conclusions.

Hsin et al. (2022) evaluated the safety and efficacy of transoral tongue suspension (TOTS) in individuals with OSA. This was a case series in 24 individuals, who were primarily male, with tongue obstruction. Inclusion criteria consisted of individuals who were 18 to 65 years of age, with a BMI of < 32 kg/m^2, an AHI of > 15/hour, a mouth opening space of ≥ 4 cm, a tongue obstruction that was discovered during drug-induced sleep endoscopy, a completed ESS, and PSG before and 6 months after surgery. All individuals received the TOTS procedure alongside UPPP. The TOTS procedure is a new technique that takes a sublabial approach to performing tongue suspension and stabilization of the tongue. Two holes are drilled into the mandible, and polypropylene is passed through the hole to the tongue base, looping back and tying the polypropylene to the mandible. Other than expected tongue swelling, no other complications were noted. Results demonstrated a decrease in AHI of 42.2 to 19.5. The authors found TOTS to be less invasive, with a success rate of 62.5%; the authors concluded that TOTS could be used as an alternative in individuals with tongue-obstructed, CPAP-failed OSA. Limitations include a small sample size, lack of comparison groups, and lack of long-term outcomes.

Bostanci and Turhan (2016) evaluated, in a systematic review, existing research for the effectiveness and safety of two tongue base suspension (TBS) techniques (Repose® system and modified TBS), with or without UPPP, in OSA. Seven studies met the eligibility criteria, mostly case series and observational studies, comparing two different TBS techniques. Four of seven studies (n = 62) used the Repose system, and three studies (n = 51) used the modified TBS technique. The success rates were higher in the studies that used the modified technique (74.5%) vs those that used the Repose system (25.8%). Ten studies, which included 300 individuals, met the eligibility criteria for TBS combined with UPPP. Seven of 10 studies included 176 individuals who used the Repose system, and three studies included 124 individuals who used the modified TBS technique. The success rates in this group were similar between the modified TBS technique (73.4%) and Repose system (67.6%). When the aggregate data for 413 individuals were compared, the modified TBS technique was found to be associated with significantly higher success rates. The authors found that the evidence supported primarily a

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grade C recommendation for the benefits of both techniques, with or without UPPP, but none of the results were convincing enough to determine which TBS technique is most effective and safe for individuals with hypopharyngeal obstruction, especially in the tongue base. A limitation of the included studies was the lack of comparison between other established approaches and OSA treatment.

Hyoid Myotomy

While the evidence for hyoid myotomy shows some promise, the current evidence for isolated hyoid myotomy for the treatment of OSA is insufficient; additional research is warranted for its safety and efficacy.

In a 2025 ECRI Evidence Analysis on the Encore™ Suspension System for treating OSA, it was concluded that there are too few data to draw definitive conclusions on safety and efficacy. No studies that compare the Encore System with other minimally invasive surgeries were identified. The available evidence consisted of three small studies with a high risk of bias and differing surgical approaches and findings.

In a clinical research response for the AirLift procedure using the Encore Suspension System (Siesta Medical, Inc.) for the treatment of OSA, Hayes (2023) concluded that the evidence is insufficient regarding safety and/or efficacy.

Van Tassal et al. (2023, included in the ECRI Evidence Analysis) evaluated the surgical outcomes in 39 individuals for adjustable hyomandibular suspension with the Encore System when performed with UPPP for the treatment of OSA. Surgical success was measured with a final AHI score of lower than 20, with a 50% or greater decline in the AHI on the postoperative sleep study. The inclusion criteria consisted of a moderate to severe diagnosis of OSA, along with CPAP failure or intolerance, hypopharyngeal obstruction, and Friedman tongue (III/IV) positions, and smaller or absent tonsils. Individuals who had not had previous UPPP underwent combined modified UPPP and hyomandibular suspension at the time of surgery. Individuals who had previously received UPPP underwent hyomandibular suspension alone. PSG or a home sleep study was completed between 3 and 9 months following surgery. Success was achieved in 30 individuals, with a mean AHI reduction from 42.0 to 10.8. Five individuals experienced procedure-related complications, which included tonsillar bleed or bleed, submental seromas at the submental incision site, and infection. The authors concluded that adjustable hyomandibular suspension is an effective treatment when combined with modified UPPP to treat individuals with moderate to severe OSA. Limitations include a small sample size, lack of control or comparison groups, and lack of long-term outcomes; future studies are warranted.

In a nonrandomized study, Shaikh et al. (2022) evaluated hyoid suspension to thyroid cartilage as both an isolated and multilevel surgery approach. Inclusion criteria consisted of adults with OSA, which was confirmed by PSG, who were intolerant of CPAP (or unwilling to try CPAP) and underwent hyoid suspension to thyroid cartilage. All individuals in the study had preoperative PSG, along with BMI and ESS scores; post operation, additional PSG was performed, along with reassessment of BMI and calculation of the AHI and ESS. Surgical success was seen in 18 of 60 individuals and defined as a 50% reduction in the preoperative AHI, along with a postoperative AHI of < 20. The authors found improvement in the mean ESS from a preoperative score of 13.1 ±6.0 to a mean postoperative ESS of 9.2 ±5.7. The AHI improved but was found to be noteworthy in the individuals with severe OSA, with improvement from 55.4 ±23.4 to 40.9 ±23.8. In addition, the obese BMI group had positive changes, with improvements in the AHI from 40.0 ±26.1 to 32.4 ±23.8. Complications occurred in two individuals; one developed small, superficial wound dehiscence, and the other developed globus sensation and intermittent dysphagia and underwent reversal of the procedure, which resulted in resolution of these symptoms. The authors concluded that hyoid suspension to thyroid cartilage was successful for individuals with OSA but particularly effective in the obese individual subset. Limitations include incomplete preoperative and postoperative home sleep study data, a lack of comparison groups, and loss to follow-up. Future high-quality studies are warranted.

Ong et al. (2017, included in the ECRI Evidence Analysis) evaluated a subset (n = 13) of 19 individuals with severe OSA who underwent hyoid myotomy and suspension surgery with the AirLift (Encore Medical, Inc.) procedure. Results demonstrated that the AHI improved from 49.9 ±16.6 events/hour prior to the operation to 29.1 ±24.9 events/hour post operation; however, the ESS showed no changes. The authors concluded that hyoid myotomy and suspension appears to be a valid option for improvement of OSA severity; however, limitations were numerous, including a small sample size, no control group, no randomization, no comparisons, and a lack of long-term outcomes.

Song et al. (2016) conducted a systematic review of hyoid surgery and its effectiveness for OSA. A comprehensive literature search was conducted that included the PubMed/MEDLINE, Embase, Google Scholar, Scopus, Cochrane Library, Web of Science, Book Citation Index–Science, Cumulative Index to Nursing and Allied Health, and Conference Proceedings Citation Index–Science databases. Inclusion criteria included adults ≥ 18 years of age, with documented OSA and isolated hyoid surgery. After screening, a total of nine articles were included, which consisted of 101 individuals for review. Overall, the authors found an improvement in AHI score by 38%, along with improvement in ESS score. The

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authors performed subanalyses that were based on primary vs secondary hyoid surgery, and both appeared successful. The authors noted that the primary surgery was more successful than the secondary, with a 46.8% vs 35.2% reduction in the AHI, respectively. In conclusion, the authors found hyoid surgery to reduce OSA severity but also noted that additional high-quality studies are needed to further validate these findings. Limitations include small sample sizes, differences in hypopnea scoring between institutions, a lack of comparison groups, and a lack of long-term outcomes.

Uvulectomy

There is insufficient evidence to conclude that uvulectomy as a stand-alone procedure is effective for the treatment of OSA.

Hayes (2023) conducted an Evidence Analysis Research Brief on uvulectomy for the treatment of OSA and found inadequate published peer-reviewed literature to evaluate the evidence of efficacy.

Radiofrequency Ablation of the Soft Palate and/or Tongue

Radiofrequency tissue volume reduction (RFTVR) involves the use of low-intensity radiofrequency energy to shrink the size of the uvula, soft palate, and/or tongue. Somnoplasty™ and Coblation® are two trade names using this technology. The procedure may be performed in conjunction with other therapies. While the evidence for radiofrequency ablation may provide support for short-term results for patients with OSA, additional larger studies and randomized trials are needed to support the long-term safety, efficacy of this procedure.

Herman et al. (2023) evaluated the safety and efficacy of multilevel RFA therapy for patients with mild to moderate OSA. Forty-three participants were recruited but only thirty completed the study. Twelve participants were lost to follow-up, and one refused to repeat the PSG after device failure. Primary outcome was AHI from baseline to 6 months postop; secondary outcomes included ESS, visual analog scale (VAS) of speech and swallowing, Functional Outcomes of Sleep Questionnaire (FOSQ) and Bed Partner Questionnaire. Participants underwent 3 radiofrequency treatments using a single-prong RFA applicator (CelonProSleep Plus; Olympus). The authors found overall approximately 50% of the participants were considered complete responders with a ≥ 50% reduction in baseline AHI and an overall AHI < 20 at 6 months, while twenty-five participants had a baseline AHI below 20 and 91% of these continued with scores below 20 after completion of treatment. Subgroup analysis for participants with moderate OSA revealed 15 of 27 demonstrated a 50% reduction of AHI with an overall AHI < 20 at completion. Secondary outcomes were measured again at six months and showed improvement in all categories. The authors concluded multilevel RFA of the soft palate and base of the tongue is a safe and effective treatment option for those patients with mild to moderate OSA and intolerant or refusal of CPAP. Limitations include lack of randomization or comparison groups, subjective questionnaires, large loss to follow-up and lack of long-term outcomes.

An ECRI (2020) clinical evidence assessment on radiofrequency ablation for treating OSA determined the evidence was of low quality and inconclusive. All 29 studies were determined to have high bias, very small sample sizes and lack of control groups. In addition, the studies assessed patients with varying severities of OSA, lacked long term outcome results and were inconsistent in radiofrequency ablation sites.

Amali et al. (2017) conducted a randomized clinical trial which compared the efficacy of modified radiofrequency tissue ablation (MRFTA) with that of uvulopalatopharyngoplasty (UPPP) in patients with mild to moderate obstructive sleep apnea (OSA). Forty patients with mild to moderate OSA were randomly divided into two groups: one for UPPP and the other for MRFTA. Evaluation was made immediately before surgery based on the apnea hypopnea index (AHI), Sleep Apnea Quality of Life Index (SAQLI) and Epworth Sleepiness Scale (ESS), and again 6 months postoperatively. The results demonstrated the postoperative AHI scores were improved significantly in both groups, although the postoperative AHI in the UPPP group was significantly lower than in the MRFTA group ($p = .02$). Comparing postoperative ESS scores in the 2 groups showed no significant difference ($p = .24$) and the SAQLI total score were significantly higher in the MRFTA group. The authors concluded MRFTA as well as UPPP can greatly improve daytime sleepiness and AHI, especially in patients with mild OSA. MRFTA proved to be more effective than UPPP to enhance quality of life of patients with OSA. Further studies with longer follow-up are required to evaluate long-term safety and efficacy of these procedures. The findings are limited by lack of comparison to other non-surgical approaches to OSA.

Baba et al. (2015) conducted a systematic review and meta-analysis to determine the efficacy of temperature-controlled radiofrequency tissue ablation (TCRFTA) to alleviate symptoms of OSA. A total of 20 studies were included in the meta-analysis. Effectiveness of TCRFTA was measured separately at the base of tongue and soft palate, and for multilevel intervention using the respiratory disturbance index (RDI), lowest oxygen saturation (LSAT), Epworth sleepiness scale (ESS) and bed partner's rating of snoring using a visual analogue scale (VAS snoring). The authors concluded that, in the short term, TCRFTA is clinically effective in reducing respiratory disturbance index (RDI) levels and symptoms of

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sleepiness in patients with OSA syndrome when directed at the base of tongue or as a multilevel procedure but had limited efficacy on the soft palate. Author noted limitations include heterogeneity between studies, short term follow-up and inclusion of lower quality studies. [publications by Atef 2005, Steward 2004a and 2004b, Terris 2002, Woodson 2001 and 2003 which were previously cited in this policy, are included in the Baba (2015) systematic review].

Transoral Robotic Surgery

TORS has been introduced as a novel tool for accessing and resecting tissue from the tongue base and hypopharynx. Based on studies using TORS to treat head and neck cancers, researchers are investigating the use of this technology for individuals with OSA, along with the procedure's safety and efficacy. Studies that include concurrent comparison groups, long-term follow-up, and sufficient power to demonstrate safety and efficacy are lacking.

In a 2025 systematic review and meta-analysis, Gupta et al. assessed the sleep outcomes and QOL with TORS in individuals in whom PAP therapy was not tolerated. Four studies (three prospective and one retrospective), including 252 individuals, were included. The retrospective study compared individuals who had TORS in addition to or as part of a multilevel surgery with those who had CPAP. The majority were male individuals who were between 40.6 and 54.3 years of age with moderate to severe OSA (AHI ≥ 15 h^{-1}). All studies reported mean AHI values and ESS scores; two reported mean pre- and postoperative oxygen saturations (SaO_2), and three reported lowest sleep SaO2 ($LSaO_2$). One reported QOL, including voice and swallowing parameters, and two studies reported prostate symptoms, overactive bladder, and erectile function. The meta-analyses were performed for the AHI, the ESS, and LSaO2. The results showed improvements in all QOL domains and no major complications in the three studies that reported this outcome. The three sleep parameters (the AHI, the ESS, and $LSaO_2$) that were included in the meta-analysis showed statistically significant improvements following TORS. The authors concluded that these findings contribute to the existing evidence on the benefits of TORS. Limitations of this study include substantial heterogeneity in anatomical and anthropometric variations between individuals. Furthermore, not all studies included the same surgery and varied between single- and multilevel procedures. Additional well-designed studies that address this heterogeneity are needed.

Lechien et al. (2021) conducted a systematic review and meta-analysis that evaluated outcomes with TORS for base-of-tongue reduction in OSAS. The outcomes measured were changes over time in the AHI, changes over time in daytime sleepiness (scored by the ESS), changes in lowest O_2 saturation levels, and surgical success rate. Overall, 1,690 individuals were included in the review. The overall summary estimates showed that the reduction in the AHI was 24.25, reduction in the ESS was 7.92, increase of lowest 0_2 saturation was 6.04%, and overall surgical success was 69%. The authors noted many weaknesses in the analysis, which limited the capacity to make definitive conclusions. Weaknesses included that (1) the profile of individuals who required TORS base-of-tongue reduction differed across studies (selection bias); (2) surgical techniques differed among studies, which may have impacted the reliability of the conclusions; and (3) there were discrepancies in the definitions of postoperative complications, which led to biases and heterogeneity between studies in the prevalence of complications. According to the authors, the main weakness is the low level of evidence of the included studies, which were mostly retrospective chart reviews. Additionally, some cases may have overlapped, as several authors were collaborating, and some individuals may have been included in more than one study. The authors suggested using improved methodology in future studies by recommending the comparison of future studies with similar and standardized criteria and definitions. (Lee et al., 2012, and Friedman et al., 2012, previously cited in this policy, are included in this meta-analysis.)

Tsou and Chang (2020) conducted a systematic review of eight articles, which compared the clinical outcomes and success rates of TORS with those of other alternative procedures such as coblation tongue base resection, upper airway stimulation, radiofrequency, CO_2 laser, and endoscopic partial midline glossectomy. The clinical outcomes that were assessed were the AHI, O_2 saturation, and ESS score. While the authors found that all the procedures significantly reduced AHI and ESS scores, along with increased O_2 saturation, no significant differences between the surgical procedures were found in operation time, success rates, or complication rates; the success rate of TORS was no more effective than that of the other alternative procedures compared. Limitations of the analysis include the lack of RCTs, lack of long-term outcomes, comparison with nonestablished approaches, and retrospective design of most of the included studies.

Lan et al. (2019, included in the Tsou and Chang, 2020, and Lechien et al., 2021, systematic reviews cited above) retrospectively compared the efficacy of TORS with that of coblation-assisted tongue base reduction surgery in patients with OSAS. Overall, 33 cases were analyzed; 16 received TORS, and 17 received coblation surgery. Both groups received concomitant uvulopalatoplasty, and surgical outcomes were evaluated by comparing the initial PSG results with a follow-up PSG within at least 3 months after the surgery. The ESS and complications were also used in the comparison between the two groups. The authors found no difference in the success rate between the two procedures. Limitations were the retrospective nature of the study and lack of comparison with established approaches to OSA; another limitation was the difficulty in comparisons due to the different surgical techniques that were used for TORS. The authors concluded

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that surgical performance, in combination with uvulopalatoplasty, is an effective approach for OSAS; however, future RCTs are needed to evaluate the efficacy of TORS.

Miller et al. (2017) conducted a systematic review and meta-analysis on the effect of TORS base-of-tongue reduction sleep-related outcomes in individuals with OSA. Studies on TORS base-of-tongue reduction as part of OSA treatment in adult individuals with pre- and postoperative AHI scores were included. Studies on TORS as treatment for diseases other than OSA were excluded. A total of six case series were reviewed, and 353 individuals met the inclusion criteria. Pooled analyses (baseline vs post-surgery) showed significant improvement in the following: the AHI (44.3 ±22.4 to 17.8 ±16.5; $p < 0.01$), the ESS (12.9 ±5.4 to 5.8 ±3.7; $p < 0.01$), lowest oxygen saturation (79.0 ±9.5 to 84.1 ±6.5; $p < 0.01$), and snoring VAS (9.3 ±0.8 to 2.4 ±2.43; $p < 0.01$). The surgical success rate was 68.4%. The cure rate was 23.8%. The authors concluded that TORS base of tongue is considered successful in the majority of adult individuals with OSA; however, further studies must be performed to optimize selection criteria among individuals to achieve higher rates of success. However, the findings are limited by the lack of a comparison group in the included studies and the retrospective nature of most of these studies. (Lee et al., 2012, Friedman et al., 2012, and Vicini et al., 2010, previously cited in this policy, are included in this meta-analysis.)

Justin et al. (2016) conducted a systematic review of the literature that evaluated the effectiveness of, complications with, and safety of TORS for the treatment of OSA. Overall, 16 studies were included. Three of these studies were case series, with comparison with historical controls, and the other were case series without a comparison group. TORS was almost always combined with other sleep surgery procedures. The summary estimate of the decrease in the AHI using TORS as part of a multilevel surgical approach was 24.0. The summary estimate of a decrease in ESS score was 7.2 and of the overall surgical success (defined as an AHI < 20 and 50% reduction) was 48.2%. Three large studies reported complication rates, with an average of 22.3%. The authors concluded that initial results for the use of TORS as part of a multilevel surgical approach for OSA are promising for select individuals. However, morbidity may be greater than that with other techniques, offsetting its advantages in visualization and precision. More prospective studies are needed to determine the optimal role of this tool. The findings are limited by the lack of a concurrent comparison group in the included studies. (Lee et al., 2012, Friedman et al., 2012, and Vicini et al., 2010, previously cited in this policy, are included in this meta-analysis.)

Distraction Osteogenesis for Maxillary Expansion (DOME)

There is insufficient quality evidence to conclude that distraction osteogenesis for maxillary expansion (DOME) is effective for the treatment of adult OSA. The published literature lacks RCTs that are needed to establish the safety, efficacy, and long-term outcomes. Future studies that include comparison groups are warranted.

In a retrospective case series, 75 patients who had a diagnosis of OSA, intolerance of CPAP, and no palatine or lingual tonsillar hypertrophy underwent a DOME procedure (Yoon et al., 2020). The custom-designed hybrid (bone borne and tooth borne) distractors were individually fabricated for each patient using 3D cone-beam computed tomography and placed with mini-screws. The expander device was activated 5 to 7 days post operation by using an axial screw for expansion daily. This continued for 3 months, but the device was kept in place for an additional 6 to 8 months. Each patient completed the ESS and Nasal Obstruction Symptom Evaluation (NOSE) questionnaires before and during the 3- to 6-month postoperative period. The patients followed the attended PSG process, which was conducted and scored 3 to 8 months following the DOME procedure. Apnea and hypopnea were both measured as well. The authors determined that the results showed significant improvements in alleviating nasal obstruction, decreasing the AHI, and improving the amount of rapid-eye-movement sleep. Limitations of the study include the small sample size, lack of parallel comparison group, and lack of long-term outcomes.

Abdelwahab et al. (2019) retrospectively evaluated a case series of 32 patients with OSA who underwent DOME by assessing subjective and objective outcomes. The patients included in the study were intolerant of CPAP, had no hypertrophy of either the lingual or palatine tonsils, had class 3 or 4 Mallampati, and had a narrow palatal arch. The procedure began with the application of the maxillary expander with fixation of four to six screws to the midpalate and maxillary bone and then performance of Le Fort I maxillary osteotomy. Post operation, the patients were taught to turn the expander daily for the next 5 weeks. NOSE and ESS scores were obtained for evaluation. The authors found that the DOME procedure widened the maxilla; therefore, it was deemed successful by improvement in the NOSE and ESS scores. Limitations include the lack of a comparison group, small sample size, retrospective design, single-institution experience, and lack of long-term outcomes.

Liu et al. (2017) described the safety and efficacy of DOME in a case series of 20 patients. Each patient underwent pre- and post-DOME PSG, along with outcome measurements from the ESS, NOSE rhinomanometry, and computed tomography measurements of the nasal floor. Following the surgical procedure, a significant decline was noted in all the measurements, along with airflow resistance; it was concluded that the DOME procedure was successful at widening the

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maxilla in all the adult patients with OSA. However, limitations include the lack of a comparison group, small sample size, and no long-term data for safety and efficacy.

Clinical Practice Guidelines

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

The AAO-HNS has several position statements on surgical treatments for OSA:

The AAO-HNS considers UPPP to be a valid and safe treatment for OSA in appropriately selected patients. “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.”

The AAO-HNS considers upper airway stimulation via the hypoglossal nerve for the treatment of adult OSA syndrome to be a safe and effective second-line treatment for patients with moderate to severe OSA who are intolerant of or unable to achieve benefit with positive pressure therapy.

The AAO-HNS recommends tongue-based suspension as effective and even comparable to genioglossus advancement when considered as part of a comprehensive approach in the medical and surgical management of symptomatic adult patients with mild obstructive sleep apnea/hypopnea syndrome and with moderate to severe obstructive sleep apnea/hypopnea syndrome with evidence of tongue base or associated hypopharyngeal obstruction. The results weaken in obese patients; therefore, this procedure has a weaker recommendation for this population.

The AAO-HNS recommends CPAP as the initial treatment modality for patients with moderate to severe OSA. “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.”

The AAO-HNS states that tongue-based procedures, including genioglossus advancement and hyoid myotomy/suspension, whether performed separately or combined, are considered effective and noninvestigational, with proven clinical results when considered as part of the comprehensive surgical management of symptomatic adult patients with mild OSA and adult patients with moderate and severe OSA with tongue base or hypopharyngeal obstruction. The utility of hyoid myotomy/suspension as a stand-alone procedure is limited with respect to AHI reduction.

The AAO-HNS states that nasal surgery can facilitate CPAP and oral appliance adherence and can improve QOL in patients with sleep apnea. As a sole procedure, it may also treat OSA in a subset of patients.

American Academy of Sleep Medicine (AASM)

A 2010 AASM practice parameter recommended surgery as a treatment option for OSA when noninvasive treatments such as CPAP or oral appliances have been unsuccessful (Aurora et al., 2010). Regarding the specific surgical options, the AASM makes the following recommendations:

- UPPP: UPPP as a single surgical procedure, with or without tonsillectomy, does not reliably normalize the AHI when treating moderate to severe OSA. Therefore, patients with severe OSA should initially be offered PAP therapy, while those with moderate OSA should initially be offered either PAP therapy or oral appliances. The clinical evidence for UPPP is of very low quality (option recommendation – either inconclusive or conflicting evidence or conflicting expert opinion). This recommendation is a change from the previous practice parameter.
- MMA surgery: MMA is indicated for the surgical treatment of severe OSA in patients who cannot tolerate or who are unwilling to adhere to PAP therapy or in whom oral appliances, which are more often appropriate in patients with mild or moderate OSA, have been considered and found ineffective or undesirable. Although the clinical evidence is of very low quality, studies tend to demonstrate consistent effectiveness in severe OSA. MMA is not well described in mild and moderate OSA, making recommendations in less severe OSA unclear (option recommendation – either inconclusive or conflicting evidence or conflicting expert opinion).
- Multilevel or stepwise surgery: Multilevel surgery, as a combined procedure or as stepwise multiple operations, is acceptable in patients with narrowing of multiple sites in the upper airway, particularly when UPPP as a sole treatment has failed (option recommendation – either inconclusive or conflicting evidence or conflicting expert opinion).
- Radiofrequency ablation (RFA): 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. The clinical evidence for RFA is of very low quality (option recommendation – either inconclusive or conflicting evidence or conflicting expert opinion).
- Laser-assisted uvulopalatoplasty (LAUP): LAUP is not routinely recommended as a treatment for OSA syndrome. LAUP does not generally normalize the AHI, and the literature does not demonstrate significant improvement in

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secondary outcomes. Some studies observed worsening of the overall AHI. The clinical evidence for LAUP is of low quality (standard recommendation – generally accepted patient-care strategy).
- Palatal implants: 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. There is limited research that adequately assesses the efficacy of palatal implants for the treatment of OSA. Available studies suggest marginal efficacy (option recommendation – either inconclusive or conflicting evidence or conflicting expert opinion).

The AASM (Aurora et al., 2016) recommends the following for the treatment of central sleep apnea syndrome (CSAS) related to congestive heart failure (CHF):
- Recommendation 1: Adaptive servoventilation that is targeted to normalize the AHI should not be used for the treatment of CSAS related to CHF in adults with an ejection fraction of ≤ 45% and moderate or severe CSA predominant, sleep-disordered breathing (STANDARD AGAINST).
- Recommendation 2: Adaptive servoventilation that is targeted to normalize the AHI can be used for the treatment of CSAS related to CHF in adults with an ejection fraction of > 45% or mild CHF that is related CSAS (OPTION).

European Respiratory Society (ERS)

An ERS guideline (Randerath et al., 2021) on non-CPAP therapies for patients with OSA makes the following recommendations for adult patients with OSA:
- Based on very-low-quality evidence, the panel suggests that HNS should not be used as first-line treatment for patients with OSA in general. However, the panel suggests that HNS compared with no treatment should be considered as a salvage treatment in patients with symptomatic OSA, who cannot be sufficiently treated with CPAP, bilevel PAP, or a mandibular advancement device and have an AHI of < 50 events/hour.
- Based on very-low-quality evidence, in adult patients with OSA, the panel suggests using either maxillomandibular osteotomy or CPAP.

National Institute for Health and Care Excellence (NICE)

Interventional procedures guidance from NICE states that the current evidence on the safety and efficacy of HNS for moderate to severe OSA is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical management, consent, and research (NICE, 2017).

Department of Veterans Affairs (VA)/Department of Defense (DOD)

The 2019 guideline for the management of chronic insomnia disorder and OSA makes the following recommendations for patients with OSA:
- In appropriate patients with mild to moderate OSA (AHI < 30 per hour), suggest offering mandibular advancement devices, fabricated by a qualified dental provider, as an alternative to PAP therapy (weak).
- For patients with OSA with an AHI of 15 to 65 per hour and a BMI of < 32 kg/m2 who cannot adhere to PAP therapy, suggest evaluation for surgical treatment with HNS therapy (weak).
- For patients with severe OSA who cannot tolerate or are not appropriate candidates for other recommended therapies, suggest evaluation for alternative treatment with MMA surgery (weak).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Oral appliances for obstructive sleep apnea (OSA) are regulated by the FDA, but products are too numerous to list. Refer to the following website for additional information (use product codes LRK or LQZ): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 18, 2025)

The Lunoa System (NightBalance BV) received 510(k) premarket notification (K180608) from the FDA on June 5, 2018. This is prescribed for the treatment of adults with positional OSA who have a nonsupine Apnea-Hypopnea Index (AHI) of < 20. It records position and movement to assess changes in position on sleep quality. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID= K180608. (Accessed September 18, 2025)

Bongo, manufactured by InnoMed Healthscience, Inc., received 510(k) approval (K180619) from the FDA on August 16, 2018. The device is an intranasal appliance that is indicated for use in the treatment of mild to moderate OSA in adults >

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66 lb. Refer to the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180619.pdf. (Accessed September 18, 2025)

The eXciteOSA device (DEN200018) is a removable tongue muscle stimulation device that delivers neuromuscular stimulation to the tongue to reduce snoring and mild OSA (AHI < 15) in patients who are aged 18 years or older. The FDA concluded this device as de novo on February 5, 2021, and classified it into Class II (product code QNO). Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id= DEN200018. (Accessed September 10, 2025)

Slow Wave DS8 received 510(k) premarket notification (K191320) from the FDA on October 2, 2020. It is used to reduce or alleviate snoring in sleeping adults with mild to moderate OSA. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID= K191320. (Accessed September 10, 2025)

The remedē System, manufactured by ZOLL, is an implantable phrenic nerve stimulator that is indicated for the treatment of moderate to severe central sleep apnea in adult patients; it received FDA approval on October 6, 2017. Refer to the following website for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id= P160039. (Accessed September 9, 2025)

The AIRvance™ Tongue Suspension system (formerly Repose), manufactured by Medtronic ENT, received 510(k) approval (K981677) from the FDA on August 27, 1999. The 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 a prethreaded suture. It is also suitable for the performance of a hyoid procedure. It is indicated for the treatment of OSA and/or snoring. Refer to the following website for additional information: http://www.accessdata.fda.gov/cdrh_docs/pdf/K981677.pdf. (Accessed September 9, 2025)

The FDA granted premarket approval on April 30, 2014, for the Inspire Upper Airway Stimulation system (Inspire Medical Systems, Inc.) (P130008). It is intended for the treatment of patients with an AHI of ≥ 20 and ≤ 65. On June 8, 2023, the FDA expanded the indications (P130008s090) for the Inspire Upper Airway Stimulation system in patients with OSA with an AHI lower limit of ≤ 15, upper limit baseline AHI from 65 to 100, and upper limited body mass index from 32 to 40 kg/m^2. The system is used in adults who have been confirmed to have experienced failure with or cannot tolerate PAP treatments and who do not have a complete concentric collapse at the soft palate level.

On August 1, 2024, the FDA approved the Inspire V Model 3150 Implantable Pulse Generator (P13008S098). The Model 3150 IPG is the new version of the currently approved Model 3028.
Refer to the following websites for additional information:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id= P130008
- https://www.fda.gov/medical-devices/recently-approved-devices/inspire-upper-airway-stimulation-p130008s090
- https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008S089B.pdf
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id= P130008S098

(Accessed September 9, 2025)

On March 20, 2023, the FDA expanded coverage of the Inspire Upper Airway Stimulation system (P130008/S089) to pediatric patients aged 13 to 18 years with Down syndrome and severe OSA (AHI of ≥ 10 and ≤ 50) who do not have complete concentric collapse at the soft palate level; are not contraindicated for or not effectively treated by adenotonsillectomy; do not have confirmation of failure; or cannot tolerate PAP therapy, despite attempts to improve adherence. Additionally, these patients have followed standard of care in considering all other alternative/adjunct therapies. Refer to the following website for additional information: https://www.fda.gov/medical-devices/recently-approved-devices/inspire-upper-airway-stimulation-p130008s089. (Accessed September 9, 2025)

In March 2023, the FDA issued a safety concern regarding jaw remodeling devices for adults. Refer to the following website for additional information: https://www.fda.gov/medical-devices/safety-communications/evaluation-safety-concerns-certain-dental-devices-used-adults-fda-safety-communication. (Accessed September 18, 2025)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2026	**Coverage Rationale** ***Obstructive Sleep Apnea*** Other Surgical Procedures • Revised list of unproven and not medically necessary procedures; added "radiofrequency ablation of the soft palate and/or tongue base" **Supporting Information** • Updated *Clinical Evidence* section to reflect the most current information • Archived previous policy version 2026T0525VV

Instructions for Use

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