Obstructive and Central Sleep Apnea Treatment

Policy Number: 2025T0525SS
Effective Date: September 1, 2025

➲ Instructions for Use

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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

Non-Surgical Treatment

Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., Polysomnography or Home Sleep Apnea Testing). Refer to the Medical Policy titled Sleep Studies for further information.

For many individuals, Oral Appliance therapy (OAT) may be an effective alternative to failed positive airway pressure (PAP) therapy. Documentation of the following is required:

- A patient presenting with symptoms of OSA has been seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine or with an Advanced Practice Provider working under the direct supervision of a physician trained in sleep medicine prior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019)
- A treating physician (MD or DO) or an Advanced Practice Provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019)
- If PAP therapy results in no therapeutic efficacy or patient intolerance or refusal, documentation from the patient's treating physician (MD or DO) or an Advanced Practice Provider must be supplied

For information on snoring and Oral Appliances, refer to the Medical Policy titled Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements.

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.

Other Non-Surgical 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)
- Removable Oral Appliances for treating Central Sleep Apnea
- Prefabricated Oral Appliance/device
- Non-surgical 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 (ALF) appliances

Surgical Treatment

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

- Moderate to severe OSA [Apnea Hypopnea Index (AHI) ≥ 15 or Respiratory Disturbance Index (RDI) ≥ 15] as determined by Polysomnography (Attended)*
- Excessive daytime sleepiness documented with an Epworth Sleepiness Scale (ESS) > 10 or with another validated tool
- PAP therapy resulted in no therapeutic efficacy or patient refusal or intolerance

In addition, the following criteria needs to be met:

- For MMA, craniofacial disproportion, or deformities with evidence of maxillomandibular deficiency
- For MO, 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 patient with moderate to severe OSA when all the following criteria are met:

- Body Mass Index of (BMI) less than or equal to 40kg/m^2; and
- AHI of ≥ 15 and ≤ 100 as determined by Polysomnography (Attended)*; and
- Total AHI < 25% for central + 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 patient 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 10-18 years with Down syndrome when all the following criteria are met:

- Diagnosis of severe OSA [as determined by a Polysomnogram (Attended)* and an AHI ≥ 10 and RDI ≤ 50 events per hour]; and
- BMI < 95th percentile for age; and
- Total AHI < 25% for central + 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 compliance; 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 non-concentric palatal collapse; and
- Used in accordance with FDA guidelines

Implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

*Polysomnography should be repeated if there has been clinically significant weight loss or gain, changes in cardiovascular disease, or there are 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):

- Laser-assisted uvulopalatoplasty (LAUP)
- Lingual suspension - also referred to as tongue stabilization, tongue stitch, or tongue fixation
- Isolated hyoid myotomy
- Stand-alone uvulectomy
- Palatal implants
- Radiofrequency ablation of the soft palate and/or tongue base
- Transoral robotic surgery (TORS)
- Distraction osteogenesis for maxillary expansion (DOME)

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 protocol titled Medical Records Documentation Used for Reviews.

Definitions

Advanced Practice Providers (APPs): Non-physician, direct care providers such as physician assistants (PAs) and advanced practice registered nurses (APRNs) (Sarzynski and Barry, 2019).

Apnea: The cessation of airflow (≥ 90% decrease in Apnea sensor excursions compared to 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 (AASM) Scoring Manual, 2023]

Apnea Hypopnea Index (AHI): 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 (AASM Scoring Manual, 2023).

Body Mass Index (BMI): A person's weight in kilograms divided by the square of height in meters. 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 (CDC), 2017].

The National Heart, Lung, and Blood Institute's (NHLBI) Practical Guide Identification, Evaluation and Treatment of Overweight and Obesity in Adults classifies the ranges of BMI in adults as follows:

- < 18.5 - Underweight
- 18.5 to 24.9 kg/m^2 – Normal Weight
- 25-29.9 kg/m^2 – Overweight
- 30-34.9 kg/m^2 – Obesity Class I
- 35-39.9 kg/m^2 – Obesity Class II
- ≥ 40 kg/m^2 – Obesity Class III

In a clinical practice guideline, the American Academy of Pediatrics (AAP; 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 ≥ 40 kg/m^2, whichever is lower based on age and sex.

Central Sleep Apnea (CSA): Characterized by sleep disordered breathing associated with decreased or no respiratory effort accompanied by excessive daytime sleepiness, frequent nocturnal wakening, or both. CSA due to hypoventilation occurs when the stimulus to breathe is removed in patients with compromised neuromuscular ventilator control. Chronic ventilatory failure due to neuromuscular or chest wall disease can produce central Apneas or Hypopneas and may occur in patients with central nervous system disease (Centers for Medicare and Medicaid Services).

Epworth Sleepiness Scale (ESS): The ESS is an 8-item questionnaire which is used to determine the level of a person's daytime sleepiness. The ESS is based on an individual's assessment of the likelihood of falling asleep in certain situations commonly encountered in daily life. Refer to the following website for further information: http://epworthsleepinessscale.com/about-the-ess/. (Accessed January 30, 2025)

Home Sleep Apnea Testing (HSAT): The use of unattended diagnostic studies to assess for 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 are determined. Not all such studies are performed at home; however, that is where the vast majority of patients undergo these tests (AASM Style Guide, 2015). Adequate HSAT occurs over a minimum of four hours and includes a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry (Kapur et al., 2017). HSAT is also referred to as out-of-center sleep testing or portable monitoring.

Hypopnea: An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or the event is associated with an arousal (AASM Scoring Manual, 2023).

Obstructive Sleep Apnea (OSA): The AASM defines Obstructive Sleep Apnea 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 AHI or RDI ≥ 5 and < 15
- Moderate for AHI or RDI ≥ 15 and ≤ 30
- Severe for AHI or RDI > 30/hour

Oral Appliance: A device inserted into the mouth for treatment of snoring or OSA (Berry, 2012). These devices can be identified as 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 AASM defines Positional Obstructive Sleep Apnea as a lower AHI in the non-supine position than in the supine position (deVries, 2015).

Respiratory Disturbance Index (RDI): 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 (AASM Scoring Manual, 2023).

Sleep Medicine Training: A one-year residency following successful completion of an accredited medical school curriculum (AASM).

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.

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., 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)
42299	Unlisted procedure, palate, uvula
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
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

CPT Code	Description
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
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 decrease 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. 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 (ICSD) identifies 6 different forms of CSA. However, the underlying pathophysiology of Central Sleep Apnea 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 patients with heart failure and increases the risk for morbidity and mortality. It is estimated that CSA may be present in 30% to 50% of patients with heart failure. Currently available treatments for Central Sleep Apnea are not widely accepted because of sparse effectiveness data, poor patient adherence, and potential safety risks. Implantable neurostimulation devices have however been studied for the treatment of CSA.

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

airway pressure (CPAP), automatic positive airway pressure (APAP), bilevel positive airway pressure (BiPAP), variable positive airway pressure (VPAP).

Non-surgical 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 non-surgical 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 (AADSM, 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 ALF 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 mimics the natural growth and development process and can widen and/or reposition the jaws.

It is the position of the American Academy of Sleep Medicine (AASM) that dentists and physicians work collaboratively managing sleep-related breathing disorders with OAT by conducting follow-up sleep testing to improve or confirm treatment efficacy along with periodic follow up visits (Ramar, 2015).

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 which pull the nasal passages open. Internal nasal dilators come in a variety of shapes and sizes are positioned just inside the nose to prop the nostrils open.

A nasal expiratory positive airway pressure (EPAP) device is a one-way valve that attaches to the nostrils before sleep. These valves use the sleeper's own breathing to create a 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 patient to use.

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

There are a variety of surgical options used to treat OSA. The intention of surgery is to create a more open airway, so obstructions are less likely to occur.

There is currently one hypoglossal nerve stimulation device cleared by the FDA. The Inspire® Upper Airway Stimulation device (Inspire Medical) treats moderate to severe OSA for 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

Non-Surgical Treatment

Devices for Treating Positional OSA

There are a variety of devices used for treating positional OSA. The available literature addressing these devices is conflicting or inconclusive and 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 treatment of positional OSA. The evidence included 6 studies: 2 RCTs, 2 RCTs with a crossover design and 2 studies with pre- and post-test designs. Overall, the evidence lacked comparative studies and long-term efficacy (Hayes, updated 2023).

In a product brief on NightBalance Lunoa by Philips Respironics, Inc., ECRI (2020) concludes that the evidence for this technology is inconclusive due to the lack of evidence available for review.

In a Cochrane review of randomized controlled trials, Srijithesh et al. (2019) compared the efficacy of positional therapy versus CPAP and positional therapy versus inactive control (sham intervention or no positional therapy intervention) in people with OSA. Eight studies with 323 randomized participants met the inclusion criteria. The comparison between positional therapy and CPAP included 72 participants, while the comparison between positional therapy and inactive control included 251 participants. 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 participants, CPAP has a greater effect on improvement of 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.

In a pilot observational study, Hidalgo et al. (2019) evaluated efficacy of sleep position therapy in fourteen patients with positional OSA for four weeks. Criteria for participants to be included in study were > 18 years, had a diagnosis of positional OSA by polysomnography (PSG), an AHI > 10/h, total sleep time (TST) ≥ 180 minutes, supine time position > 30% and no previous CPAP treatment. A complete overnight PSG was performed at baseline and at 1 and 4 weeks after starting the study. After the initial PSG, each participant was given a vibrating positional device that was placed on the patient's forehead via a sticker; this device was to be used for the next four weeks. The device starts vibrating with increasing intensity and has four different vibration intensities when the patient lies in the supine position for more than 30 seconds. The vibration stops when the patient changes from the supine to the non-supine position. The authors found the use of this vibrating device decreased the median AHI in patients up to 31.6%; in addition, improvement in oxygen saturation was observed. It was concluded this type of device could be useful for patients with positional OSA, but further studies are warranted. Limitations included small participation size, limited follow-up for long-term compliance and lack of a placebo group. Further RCTs are required to confirm the efficacy of this device placed on the patient's forehead.

A multicenter trial randomized ninety-nine patients with mild to moderate positional OSA (POSA) to either a sleep position trainer (SPT) group or one with oral appliance therapy (de Ruiter et al. (2018), included in the Hayes Report above). SPT is a newer option for treating patients with positional OSA and the goal of the authors was to investigate the long-term efficacy, adherence, and quality of life for this device. Eligible participants had a diagnosis of mild to moderate POSA (AHI of 5-30) and spent 10-90% of their sleep time in the supine position. The SPT group utilized 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 the AHI and oxygen desaturation index (ODI) were significantly reduced for both treatment groups at the 3- and 12-month follow up visits along with similar results for adherence of the device usage in both groups. The main limitation of this study was the higher dropout rate over the course of 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 patients with supine OSA. Seven studies with 108 participants met the inclusion criteria in comparing any type of positional therapy (e.g., vibratory vests, foam backpacks, tennis balls) with any other intervention. In positional techniques compared to non-standard therapy, four studies included in the meta-analysis showed significant reduction in AHI favoring the positional techniques. In positional techniques compared to CPAP therapy, 2 studies showed significant reduction in AHI favoring CPAP. One study showed a significant reduction in AHI favoring the sleep position trainer when compared to a tennis ball vest. Additionally, the evidence suggested that there was no significant effect on sleepiness or sleep efficiency when position modification therapy (PMT) was compared to no treatment or the CPAP treatment. Although it was identified that participants have greater compliance with positional techniques than CPAP in the short-term, the authors found long-term results remain unclear specifically for electronic vibratory devices. In addition, CPAP is more effective at reducing AHI. Future studies should include multiple positional devices using an adequate number of participants, 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. In order to prove a benefit of 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 on 10 male participants and evaluated the airflow rate of the new nasal breathing stent (NBS) against those of existing nasal dilators. The following were the comparator dilators used: Max-Air Nose Cones® (NC) and Mute with hole® (MT) for internal nasal use, and Breathe Right® (BR), 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; high speed camera was used to measure and capture airflow velocity when the appliance was utilized. The authors found the mean velocity was significantly higher for the NBS than the other appliances used. Limitations included small sample size and lack of long-term OSA-specific outcomes. While this new device shows promise, further

investigation on patients with OSA is necessary to examine the effects of NBS when compared to that of an oral appliance or CPAP.

Gelardi et al. (2019) studied 19 adult patients with a diagnosis of OSA and whether the use of internal nasal dilator was able to significantly reduce AHI and the oxygen desaturation index. Subjective parameters were evaluated by the patients, and included perception of nasal obstruction, sleep quality, and olfaction – these were all measured by a visual analogue scale (VAS). The VAS scores ranged from zero for completely blocked nose to 10, which indicated a completely patent nose, additional evaluation for smell, quality of sleep and satisfaction. Daytime sleepiness was evaluated with the Epworth Sleepiness Scale (ESS) -- an ESS score of ≥ 10 was considered excessive daytime sleepiness. Cardiorespiratory nocturnal monitoring was performed on 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 the use. The results indicated 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 the results showed that Nas-air® is a new internal nasal dilator potentially capable to significantly improve respiratory outcomes and sleep quality for patients with OSA. However, the study had some limitations including lack of comparison with established treatments, the open-label study design, the lack of follow-up, and the 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 obstructive sleep apnea (OSA). Five studies were found for internal dilators and nine studies for external dilators. Twelve of the fourteen studies showed no significant change in the apnea-hypopnea index (AHI) with the use of the nasal dilators. Furthermore, the meta-analysis of the combined studies did not show any benefit of the device. The essential limitation of this study is the lower quality of published studies evaluating nasal dilators. Most studies were individual case-control or prospective case series studies with often smaller sample sizes lacking 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. In order to prove a benefit of these appliances, future research should demonstrate the clinical utility and long-term safety and efficacy of these devices.

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 obstructive sleep apnea (OSA) following continuous positive airway pressure (CPAP) withdrawal in patients with moderate-to-severe OSA. The goal of the study was to determine if patients with OSA could occasionally substitute the Provent device for their CPAP. Sixty-seven patients with OSA 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 apnea-hypopnea index (AHI) before CPAP treatment was 38 events per hour. Primary outcomes included for the active Provent versus the placebo Provent were OSA severity (oxygen desaturation index (ODI), AHI and Epworth Sleepiness Scale (ESS) score. Secondary outcomes for the active Provent versus the placebo Provent included ODI from ambulatory pulse oximetry and blood pressure (BP). For CPAP versus the active Provent or CPAP versus the placebo Provent, secondary outcomes included ODI/AHI, ESS and BP. OSA recurred in the active Provent and placebo Provent groups, and there was no significant difference in ODI, AHI, and ESS between active Provent and placebo Provent at 2 weeks. ODI from ambulatory pulse-oximetry and BP at 2 weeks were not different in the active Provent versus the placebo Provent groups. ODI, AHI and BP, but not ESS, were significantly higher in the active Provent and placebo Provent groups compared with CPAP. The authors concluded that Provent cannot be recommended as an alternative short-term therapy for patients with moderate to severe OSA already on CPAP. The study provides evidence for inferiority of the Provent nasal device compared to CPAP and for the ineffectiveness of nasal dilator when compared to a placebo device.

Berry et al. (2011) conducted a multicenter randomized controlled trial investigating the efficacy of the Provent nasal device, a nasal expiratory positive airway pressure (EPAP) device for treating OSA. Two hundred and fifty patients 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 these, 173 had an AHI > 5/hour on the device-off night and comprised the modified intention to treat (mITT) group (92 EPAP, 81 sham). One hundred ninety-five patients in the ITT group (100 EPAP, 95 sham) and 144 patients in the mITT group (77 EPAP, 67 sham) completed the 3-month study. All patients underwent a baseline clinic evaluation that included the Epworth Sleepiness Scale (ESS). Polysomnography (PSG) was performed on 2 non-consecutive 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 to device-off nights and the difference was significantly greater than with the sham device (52.7% versus 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 to device-off nights. The authors concluded that nasal EPAP significantly reduced the AHI and improved subjective daytime sleepiness compared to the sham treatment in patients with mild to severe OSA with excellent adherence. This study is limited by short follow-up, loss to follow up, lack of comparison with established treatment approaches, patient-reported adherence, a large number of exclusion criteria and a modified intention to treat 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 trial. This study was designed to evaluate the long-term effectiveness of the Provent nasal device among participants who had responded in the initial study. Forty-one patients from the EPAP arm who met adherence and efficacy criteria were continued on therapy and returned for polysomnography (PSG) after 12 months of treatment. From the analyzable subject cohort (n = 34), results from the 12-month PSGs were compared against their baseline results. Median AHI was reduced from 15.7 to 4.7 events/h (week 1 device-off versus month 12 device-on). The decrease in the AHI (median) was 71.3%. The Epworth Sleepiness Scale 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 trial. As with the original trial, this study is limited by patient-reported adherence and a large number of exclusion criteria. Additionally, analyses limited to responders is inherently biased to assess objectively the impact of an intervention. Furthermore, a potential for bias exists due to manufacturer sponsorship of the study.

Walsh et al. (2011) evaluated tolerability, short-term efficacy, and adherence of the Provent nasal device, an EPAP nasal device, in 59 patients with OSA who refused CPAP or used CPAP less than 3 hours per night. After demonstrating tolerability to the EPAP device during approximately 1 week of home use, 47 patients (80%) underwent a baseline polysomnogram (PSG1). Forty-three patients met AHI entry criteria and underwent PSG2 within 10 days of PSG1. Twenty-four patients (56%) met prespecified efficacy criteria and underwent PSG3 after 5 weeks of EPAP treatment. Compared to PSG1, mean AHI was significantly lower at both PSG2 and PSG3. For most patients AHI at PSG3 was similar to AHI at PSG2. Device use was reported an average of 92% of all sleep hours. The authors concluded that improvements in AHI and Epworth Sleepiness Scale (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 lack of randomization and 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 CSA

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 demonstrating 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 versus custom made mandibular repositioning devices (MRD) in the management of mild to moderate obstructive sleep apnea (OSA). Thirty-five participants were randomized into receiving either the ready-made or custom made MRD. The primary outcome was measurement of AHI which was measured by an overnight home sleep study. The authors demonstrated custom made devices for MRD had a significant impact in the treatment of OSA in contrast to 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 included small number of participants and a withdrawal of almost 30% of the patients after the 3-month treatment interval.

Non-Surgical Electrical Muscular Training

The evidence for non-surgical electrical muscular stimulation is limited; there is little quality evidence to demonstrate the safety or efficacy in the use for 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 obstructive sleep apnea and snoring. The device works by delivering electrical muscle stimulation through a mouthpiece that sits around the tongue. The system consists of a mouthpiece, a rechargeable control unit, and a mobile app that allows the

patient 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, updated in 2024, identified three single-arm studies of poor or very poor quality were identified and suggest there is no clear support for using eXciteOSA for the treatment of primary snoring or mild OSA.

An ECRI (2022) clinical evidence assessment identifies very low-quality evidence from three pre-post studies which suggests eXciteOSA may improve symptoms in some patients 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 patients with mild OSA. Limitations include high risk bias, lack of blinding and lack of long-term efficacy. The authors conclude that the evidence is inconclusive. Further RCTs with long-term outcomes are needed to address these gaps.

Moffa et al. (2022) conducted a systematic review to evaluate the efficacy of non-invasive electric stimulation devices for the treatment of primary snoring and obstructive sleep apnea. The review included literature published through September 2021 that reported use of an intraoral device that performs an awake neuromuscular electric stimulation of the tongue muscles. Four studies met 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 the non-invasive electric stimulation devices improved snoring by 50%. Additionally, two studies showed a significant apnea-hypopnea index improvement in mild OSA. The authors suggested intraoral non-invasive electrical stimulation devices can be a valid option for snoring. Limitations included lack of comparison to other treatment approaches or sham, as well as analyses 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).

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 mandibular repositioning devices which open the jaw vertically for OSA.

Morning Repositioning Devices

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

Epigenetic Appliances

Epigenetic appliances are intraoral devices similar to an orthodontic retainer in appearance. The premise is that when 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, TMJ disorders, sleep apnea and chronic headaches. There is no quality evidence to support the efficacy of this therapy for OSA.

Advanced Lightwire Functional (ALF) Appliances

The ALF 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 mimics the natural growth and development process and can widen and/or reposition the jaws. There is no quality evidence to support the efficacy of this therapy for OSA.

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 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 PAP recommends continuous positive airway pressure (CPAP) or automatic positive airway pressure (APAP) for ongoing treatment of OSA in adults (Patil, 2019).

AASM makes the following recommendations regarding oral appliance therapy (Ramar et al., 2015):

- When oral appliance therapy 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 non-custom 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 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 oral appliance therapy 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 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 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 Dental Sleep Medicine (AADSM)

In a committee update on the use of oral appliance therapy, the AADSM (2022) provides guidance for patient examination, screening, treatment, education, and follow-up in patients with snoring and OSA. The AADSM indicates the patient must be referred to a medical provider for the diagnosis of OSA as this is the responsibility of the medical physician. If OSA is diagnosed, the patient may be referred to a qualified dentist (QD) for further evaluation of OAT. While OAT is the first line of treatment for snoring, in cases of OSA, OAT may be recommended in patients when they have been intolerant or have had failure to PAP. “The QD should collaborate with the medical provider(s) to develop properly sequenced treatment(s), involving either solo OAT or OAT in combination with non-surgical or surgical therapies.”

American Association of Oral and Maxillofacial Surgeons (AAOMS)

In a position paper on evaluation and management of OSA, the AAOMS reveals 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 failed 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 American College of Physicians (ACP) developed a clinical practice guideline on the management of obstructive sleep apnea (OSA) in adults (Qaseem, et al., 2013). The guideline makes the following recommendations:

- All overweight and obese patients diagnosed with OSA should be encouraged to lose weight. (Grade: strong recommendation; low-quality evidence).
- Continuous positive airway pressure treatment is recommended as the initial therapy for patients diagnosed with OSA. (Grade: strong recommendation; moderate-quality evidence).

European Respiratory Society (ERS)

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

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

Surgical Treatment

In the TEAMUP (Tonsillectomy and Modified Uvulopalatopharyngoplasty) RCT of ninety patients with moderate to severe OSA, Sundman et al. (2022) investigated whether a modified UPPP was more effective than a tonsillectomy. Participants were aged 30 to 65 years, had an AHI score of > 15 events/hour, tonsil size of 2, 3 and 4 on the Friedman scale and failure of non-surgical treatment. All participants were blinded, and a 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). Patients were not told which surgical procedure (mUPPP vs TE) they had received neither after surgery nor during follow-up. Each participant underwent two PSGs, 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 postop PSG. Primary outcome was a change in the AHI score from baseline to 6 months postop. The authors found the AHI score decreased from 51 to 28 events/hour for the mUPPP group and 56.9 to 24.7 events/hour for the TE group. The ESS score also demonstrated positive results with seventy-eight patients responding to the questionnaire; scores decreased from a baseline score of 9.1 to 5.8 at 6 months for the mUPPP group and 11.4 to 7.2 for TE group. The authors concluded the study did not validate that mUPPP was any more effective than the TE; in fact, there may have been slight bias for the TE procedure. Future studies including long-term outcomes are warranted. Limitations included small sample size, inability to generalize the results to overall population, and lack of long-term outcomes.

In a case series of 65 participants, Sundman et al. (2021) investigated the long-term effectiveness of a modified uvulopalatopharyngoplasty (UPPP) for patients with OSA. Eight years after receiving a UPPP for OSA, sixty-five patients were offered a re-evaluation of their condition with a polysomnography and the Epworth Sleepiness Scale (ESS); results were compared to their 2-year follow-up results. The authors found the modified UPPP was effective as a long-term solution for OSA patients although the AHI did decrease over time. Limitations included small sample size, the lack of comparison groups, and lack of female participants making generalization difficult.

A systematic review and meta-analysis performed by Zhou et al. (2021) evaluated the efficacy of eight different variations of maxillomandibular advancement (MMA) surgical treatment for patients with OSA. Eight articles including 227 patients were included. All studies included AHI results, but only five studies reported SpO2, and six studies reported post-op ESS scores. The authors found MMA combined with uvulopalatopharyngoplasty with uvula preservation (HUPPP) had the highest efficacy rate than any of the other MMA combinations. Limitations included the small number of articles, in addition to the small number of patients within 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), thus not providing a satisfactory analysis.

The American Academy of Sleep Medicine (AASM) commissioned a task force of sleep medicine experts to conduct a systematic review and meta-analysis on patients with a diagnosis of OSA and referred for surgical intervention (Kent et al., 2021). 274 articles, including RCTs and observational studies, met the criteria and were included in the analysis. The task force concentrated on four questions pertaining to the use of surgery to treat adult OSA: 1) Surgical treatment of patients who were intolerant or unaccepting of PAP, 2) Surgical treatment of patients with obesity with bariatric surgery, 3) Surgical treatment of patients to facilitate PAP use, and 4) Surgical treatment as an initial therapy in patients with a major upper airway anatomical abnormality. For surgical treatment of patient's intolerant or unaccepting of PAP, a total of 4 RCTs and 239 observational studies were analyzed; included in this were patients with oropharyngeal obstruction. Two RCTs and 15 observational studies were found addressing surgical treatment as an initial therapy in patients with a major upper airway anatomical abnormality. The participants in the two RCTs were mostly male with a mean BMI < 30 kg/m^2 and diagnosed with moderate to severe OSA; they also exhibited tonsillar hypertrophy with velopharyngeal obstruction and were intolerant 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 and for patients who are intolerant or unaccepting of CPAP due to risk of bias associated with observational studies and imprecision within the RCTs. Several areas were identified that warrant further investigation, but it was demonstrated that patients with major upper airway obstruction benefit from surgery and appropriate referral of patients with OSA for surgical consultation is vital. Limitations included variability in procedure choice and technique, non-standardized reporting of outcomes, small and heterogeneous study populations and selection bias, and lack of binding. The authors identified further studies are required to better evaluate the patient's preference for PAP vs surgery as a first line therapy, additional comparative studies comparing surgery to medical therapies for OSA and long-term assessment of the surgical interventions.

MacKay et al. (2020) assessed the efficacy of a multi-level surgery (modified UPPP and minimally invasive tongue volume reduction) as a treatment for patients with obstructive sleep apnea (OSA) compared to conventional treatment. The multi-center randomized controlled trial included patients that were 18–70 years of age with moderate or severe OSA that was defined as an AHI of 15-30 and > 30 events/h of sleep. Additional inclusion criteria were BMI < 38, ESS > 8, failure of medically supervised attempts to use CPAP and, when appropriate, failure or refusal of use of a mandibular advancement

device. The primary outcome measures were AHI and ESS at 6 months. 102 patients were included in the study of which 51 were randomized to the intervention arm and 51 were randomized to the control arm. For the intervention group, the mean AHI was 47.9 and ESS was 12.4 pre-procedure and at 6 months post-procedure AHI was 20.8 and ESS was 5.3. For the medical management group, the mean AHI was 45.3 and ESS was 11.1 at baseline and at 6 months the mean AHI was 34.5 and ESS was 10.5. The authors concluded that multi-level upper airway surgery resulted in significant reductions in frequency of sleep apnea and daytime sleepiness for patients with moderate to severe OSA in which prior conventional treatment failed. Limitations noted include establishment of long-term effectiveness, reduced generalizability due to exclusion criteria and underrepresentation of women, and inability to blind patients which may influence self-reported sleepiness.

Gao et al. (2019) conducted a systematic review and network meta-analysis on 89 randomized controlled trails which compared and ranked the effectiveness of minimally invasive treatments for adult OSA. Since only simple surgeries performed under local anesthesia (palatal implants, laser-assisted uvulopalatoplasty, uvulopalatopharyngoplasty, septoplasty, and radiofrequency tissue ablation) were the focus, major surgeries such as maxillomandibular advancement and bariatric surgery were excluded. The findings of the authors support the guidelines that the first line treatment options for adult OSA to include PAP and MAD. Behavioral treatment which included exercise, physical therapy (PT), and Lifestyle Modification (LM) -- via dietary control and weight loss, Myofunctional Therapy (MT) and Cervico-mandibular Support Collar (CMSC) were also included in the analysis. Results demonstrated that although exercise and CMSC yield insignificant effectiveness in AHI reduction when compared to no treatment, they rank first and second, respectively, in reducing ESS. In contrast, PT demonstrates significant effectiveness in AHI reduction but insignificant improvement in ESS. Among all interventions, PT ranks third in reducing both AHI and ESS. Results indicated that LM alone cannot be considered as an effective alternative to OSA treatment therefore LM lacks efficacy and ranks last in the management of adult OSA. The authors concluded that simple surgical procedures may not be curative for adult OSA; even though they improve scores for AHI or ESS, the findings are considered insignificant when compared with no treatment. According to the authors, at present, maxillomandibular advancement performed under general anesthesia has been recognized as an effective treatment for OSA because it improves polysomnographic parameters comparable to CPAP. The study is limited by the indirect nature of comparisons in network meta-analyses.

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 patients with OSA. 462 patients from twenty studies were included for analysis. The authors found substantial improvements were seen following surgical intervention in outcome measures for AHI, RDI, ESS and LSAT and concluded MMA is a successful treatment option for OSA. Limitations included selection bias for article identification, only one article was an RCT, lack of parallel comparison group undergoing a different treatment, and few studies reported MMA as an isolated primary procedure.

In a 2017 overview of eleven systematic reviews, Tan et al. assessed the evidence for the 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 patients, as well as those with cleft lip and palate, syndromic or distraction osteogenesis were excluded. Two SRs reported on the effects of various orthognathic surgeries on the pharyngeal airway, and eight focused on MMA and other surgical treatment related specifically to OSA. Additionally, were two 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 of MMA and a significant reduction in 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 pre-operative values. This review is limited by the quality of the SRs that were reviewed, and the authors recommended it be read with caution.

Zaghi et al. (2016) conducted a meta-analysis on the success and effectiveness of MMA for OSA. Forty-five articles were included for review which included 518 patients. Study inclusion criteria included adults 18 years of age and older who underwent an MMA along with preop and postop outcomes for AHI and/or RDI. In addition, the following individual patient data was 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 the AHI or RDI score. The authors found 90% of patients experienced improvements in their AHI and RDI scores following surgical intervention. The authors' concluded MMA is a highly effective treatment for OSA that was proved by substantial improvements in both AHI and RDI. Limitations included studies that included only reported patient data thus introducing selection bias and absence of long-term follow up (i.e., 10-15 years post-surgical treatment) and, in general, lack of comparison group of participants undergoing a different treatment approach.

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

In a 2015 retrospective cohort study, Butterfield et al. investigated the linear and volumetric morphologic changes that occur in the pharyngeal airway in 15 patients after treatment of OSA using MMA via a LeFort I osteotomy and bilateral sagittal split osteotomy with rigid internal fixation. Inclusion criteria included age 18-65, a diagnosis of OSA from an in clinic polysomnogram, an obstruction in the oropharynx using the Mallampati classification, BMI less than 40, and inability to tolerate C-PAP after a minimum of 3 months. The nasopharynx and oropharynx were measured as the volume from the posterior nasal spine to the tip of the uvula and the tip of the uvula to the tip of the epiglottis, respectively. Patients underwent lateral cephalometric and cone beam computed tomography (CBCT) radiographs pre-operatively and post-operatively at 2 and 29 months. The surgical changes of the posterior airway space and occlusal plane rotation were measured using Cephalometric for Orthognathic Surgery analysis. The results showed that after surgery, the AHI decreased by 83.1% and the ESS decreased by 53.3%. The percent of REM sleep increased by 68%. The total airway volume (AV) had increased by 80.43%, the minimal cross-sectional area (minCSA) increased by 212.59%, airway index (AI) had increased significantly by 109.13% ($p < .001$), the airway length (AL) had decreased by 12.63%, and the posterior airway space (PAS) had increased by 106.28%. There was a significant increase in both the nasopharyngeal volume and the oropharynx volume of 76% and 89% respectively. The authors concluded that MMA increases the total AV, tightens the lateral pharyngeal walls, and changes the shape of the airway from circular to oblong, resulting in an airway that is less likely to collapse. This study is limited by the lack of comparison group, a small sample size and a retrospective design.

Browaldh et al. (2013) conducted a prospective single center randomized controlled trial to assess the efficacy of UPPP in patients with obstructive sleep apnea syndrome (OSAS). Inclusion criteria were men and women > 18 years of age; AHI ≥ 15 events per hour of sleep; ESS ≥ 8; marked daytime sleepiness ≥ 3 times a week; body mass index < 36 kg/m^2; Friedman stage I or II; and failure of CPAP and mandibular repositioning device that had not been used in the previous three months. The primary outcomes measurement was the change in AHI measured by polysomnography (PSG) at 6 months. 65 patients were included in this study, 32 of which were in the treatment arm and 33 in the control arm. At the 6-month follow-up, the AHI for the intervention group decreased by 60% from 53.3 (19.7) events/hour to 21.1 (16.7) events/hour and the control group mean AHI decreased by 11% from 52.6 (21.7) events/hour to 46.8 (22.8) events/hour. This was a significant difference between the two groups. The limitation in this study was a lack of longer follow-up duration which the authors acknowledged and noted that they considered it unethical to leave patients in the control group untreated for a longer time. Those patients in the control group received surgical treatment after the second evaluation with PSG.

Caples et al. (2010) conducted a systematic review and meta-analysis of literature reporting outcomes following various upper airway surgeries for the treatment of OSA in adults, including maxillomandibular advancement (MMA), pharyngeal surgeries such as uvulopalatopharyngoplasty (UPPP), laser assisted uvulopalatoplasty (LAUP) and radiofrequency ablation (RFA), as well as multi-level and multi-phased procedures. The authors found that the published literature is comprised primarily of case series, with few controlled trials and varying approaches to pre-operative evaluation and postoperative follow-up. Surgical morbidity and adverse events were reported but not systematically analyzed. The change in the apnea-hypopnea index (AHI) was the primary measure of efficacy. Substantial and consistent reductions in the AHI were observed following MMA; adverse events were uncommonly reported. Outcomes following pharyngeal surgeries were less consistent; adverse events were reported more commonly. Papers describing positive outcomes associated with newer pharyngeal techniques and multi-level procedures performed in small samples of patients appear promising. The authors concluded that further research is needed to better clarify patient selection, as well as efficacy and safety of upper airway surgery in those with OSA. The findings are limited to the lack of comparison group in several of the included studies.

Hypoglossal Nerve Stimulation

Heiser et al. (2023) compared HNS therapy to PAP treatment with outcome parameters of sleepiness, AHI, and effectiveness. 126 individuals diagnosed with OSA were included for analysis and separated into two cohorts; 63 patients

treated with PAP and the other 63 had been treated with HNS. PAP was the first line of treatment and then if failure or patient intolerance, HNS was the second line of treatment. The ESS questionnaire was used to report sleepiness assessed at baseline and again at 12-months; the baseline ESS was higher in the HNS cohort than in the PAP group. The primary endpoint for the study was the assessment of the effect of the two treatments on sleepiness. At 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 both groups experienced improvements in sleepiness, but the authors demonstrated that HNS therapy was superior when it came to improving daytime sleepiness. Data for HNS therapy was 7.5 ±4.7 versus 10.8 ±5.6 for PAP treatment; the authors felt the 3.3-point difference was not statistically significant. Among the patients treated with PAP, it was identified that CPAP was the most used (68%), followed by automated PAP (19%) and finally bi-level PAP (13%). Limitations included lack of comparison groups and long-term follow-up.

In a clinical evidence assessment by ECRI (2021), evidence from one systematic review and six non-randomized comparison studies suggest that the Inspire® Upper Airway Stimulation (UAS) system may outperform other surgeries in improving sleep and reducing OSA symptoms. The authors note that the evidence is somewhat favorable with the following limitations in the body of evidence: short follow-up, small sample sizes, retrospective design, and patient attrition. Future controlled studies that provide long-term data are needed to validate Inspire benefits and compare it against CPAP therapy.

A Hayes report concluded that the overall quality of the evidence evaluating hypoglossal nerve stimulation (HNS) for treating OSA is very low. However, evidence does suggest that the intervention is relatively safe and may reduce the severity of OSA and improve PROMs (excessive daytime sleepiness, function, quality of life) for patients with OSA that have failed or are intolerant to CPAP therapy. Stimulation of the hypoglossal nerve may provide a treatment option for patients with moderate-to-severe OSA for whom CPAP has failed to provide relief, but the procedure may carry risks for complications and post implantation surgical procedures. Additional good-quality comparative studies with larger sample sizes are needed to define the patient population 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 treatment of moderate to severe OSA comparing before and after treatment. Inspire was implanted in 68% of the patients with success rate of 75% at five years. In contrast, 18% of the patients were treated with the Aura 6000 system with a success rate of 35%. All primary clinical outcomes such as AHI, ODI and ESS showed improvement at the 12- and 60-month assessment. Several minor adverse effects were experienced by several patients, but all were non-serious and found resolution. While the authors found HNS was an effective and safe surgical procedure for patients with OSA, a subgroup analysis demonstrated there is not enough data to compare clinical outcomes to different stimulation systems. The STAR trial (see Strollo and Woodson below) was the only study to include long-term data, a limitation of this analysis along with lack of comparison groups or RCTs.

Kompelli et al. (2018) performed a meta-analysis of available HNS studies to analyze objective and subjective outcomes and side effects of treated OSA. A comprehensive literature search of PubMed and Scopus was performed, and 16 case series were found that included the analysis of 381 patients. At 6 months, the mean Sleep Apnea Quality of Life Index (SAQLI) improved by 3.1 (95%CI, 2.6-3.7). At 12 months, the mean AHI was reduced by 21.1 (95%CI, 16.9-25.3), the mean ODI was reduced by 15.0 (95%CI, 12.7-17.4), the mean ESS was reduced by 5.0 (95%CI, 4.2-5.8), the mean Functional Outcomes of Sleep Questionnaire (FOSQ) improved by 3.1 (95%CI, 2.6-3.4). Unexpected events of the study included pain, tongue abrasion, and internal/external device malfunctions. The authors concluded that HNS is a safe and effective treatment for CPAP refractory OSA, however further studies comparing HNS to other therapies are required.

The Stimulation Therapy for Apnea Reduction (STAR) trial (Strollo et al. 2014, included in the Hayes and ECRI reports and Costantino (2020) above) evaluated the clinical safety and effectiveness of upper airway stimulation at 12 months for the treatment of moderate to severe obstructive sleep apnea. Using a multicenter, prospective case series design, an upper airway stimulation device was surgically implanted in patients with obstructive sleep apnea who had difficulty either accepting or adhering to CPAP therapy. The primary outcome measures were the apnea-hypopnea index (AHI; the number of apnea or hypopnea events per hour, with a score of ≥ 15 indicating moderate-to-severe apnea) and the oxygen desaturation index (ODI; the number of times per hour of sleep that the blood oxygen level drops by ≥ 4 percentage points from baseline). Secondary outcome measures were the ESS, the FOSQ, and the percentage of sleep time with the oxygen saturation less than 90%. The study included 126 participants; 83% were men. The mean age was 54.5 years, and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 28.4. The median AHI score at 12 months decreased 68%, from 29.3 events per hour to 9.0 events per hour; the ODI score decreased 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 quality of life. In the randomized phase, the mean AHI score did not differ significantly from the 12-month score in the nonrandomized phase among 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) among 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 obstructive sleep apnea. The lack of a control group limits the validity of the results of this study. This study was funded by Inspire Medical Systems.

Follow-up studies of the same patient population at 18 and 36 months, indicate that the treatment effects are maintained over time. Limitations are the same as 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 (2020) above) assessed the efficacy and durability of upper airway stimulation via the hypoglossal nerve on obstructive sleep apnea (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 III trial of 126 implanted participants. Participants were randomized to either therapy maintenance ("ON") group or therapy withdrawal ("OFF") group for a minimum of 1 week. Short-term withdrawal effect as well as durability at 18 months of primary (apnea hypopnea index and oxygen desaturation index) and secondary outcomes (arousal index, oxygen desaturation metrics, Epworth Sleepiness Scale, Functional Outcomes of Sleep Questionnaire, snoring, and blood pressure) were assessed. Both the therapy withdrawal group and the maintenance group demonstrated significant improvements in outcomes at 12 months compared to study baseline. In the randomized assessment, therapy withdrawal group returned to baseline, and therapy maintenance group demonstrated no change. At 18 months with therapy on in both groups, all objective respiratory and subjective outcome measures showed sustained improvement similar to those observed at 12 months. The authors concluded that withdrawal of therapeutic upper airway stimulation results in worsening of both objective and subjective measures of sleep and breathing, which when resumed results in sustained effect at 18 months. The authors state that reduction of obstructive sleep apnea severity and improvement of quality of life 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 the lack of subject or investigator blinding. This study was funded by Inspire Medical Systems.

Down Syndrome (DS)

Rodriguez Lara et al. (2024) conducted a systematic review on the advances in the use of hypoglossal nerve stimulation in adolescents with Down syndrome and persistent OSA after adenotonsillectomy (AT) and trial of CPAP therapy. Ten studies comprised of 121 patients that investigated the use of HNS in children, were included, 3 prospective clinical trials, 1 cross-sectional study, 4 case series, and 2 case reports. Outcomes included changes in AHI, quality of life and sleep measures (using the OSA-18 survey, a validated, disease-specific survey that includes questions in 5 domains (sleep disorders, physical distress, emotional distress, diurnal problems, and caretaker occupation). The results showed improvement in AHI across all studies, and ranged from 48-93%, with the effectiveness largely based on one prospective clinical trial of 42 participants. In general, the QOL and ESS questionnaires also showed significant improvement, even in patients with post therapy 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 DS and persistent OSA. These findings cannot be extrapolated to pediatric patients without DS and further research in that population is required.

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 PubMed, Web of Science, Embase, and Scopus databases. A total of nine studies (3 cases series, 3 prospective studies and 3 case reports) were found that included 106 adolescents, 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 demonstrated a decrease in the AHI score. Three studies reported adverse events such as tongue or mouth pain, rash, inflammation, insomnia, pneumothorax, and swallowing or speech-related problems. The authors concluded HNS was found to be an effective treatment for OSA in Down syndrome adolescents and was considered a better option than CPAP. Limitations included small sample sizes and case reports, lack of control groups, and lack of long-term outcomes; future large-scale, prospective, randomized controlled studies are required.

Yu et al. (2022, included in the Liu 2022 and Rodriguez Lara 2024 systematic reviews above) evaluated the safety and effectiveness of upper airway stimulation for adolescent patients with Down syndrome and severe OSA. This phase one prospective study included 42 Down syndrome adolescents (at least 10 years of age or < 22 years of age) with severe OSA. All patients underwent a polysomnography prior to enrollment if they did not have one in the previous six months and then underwent a drug-induced sleep endoscopy (DISE) under sedation with propofol and/or dexmedetomidine and

were excluded if they had circumferential palatal collapse. Eligible patients received a hypoglossal nerve stimulator implant which was activated in the clinic one month after placement. Follow-up polysomnograms were obtained at 2, 6, and 12 months. The most common adverse event was tongue or oral discomfort or pain, which occurred in 5 patients and was temporary. Some patients exacerbated complications (such as site infection, postop 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 AHI and 27 of the 41 patients achieved this; the mean percentage change in AHI was –51.2%. At twelve months, the mean change in AHI was a decrease of 12.9 events/hour. The authors concluded this cohort of patients had a high therapy response rate along with improvement in their quality of life after the implant of an upper airway stimulation device. Limitations include small sample size, lack of control group, and lack of long-term outcomes.

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

Implantable Neurostimulation Devices for the Treatment of Central Sleep Apnea (CSA)

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

A 2024 Hayes technology assessment concluded there is 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 consisting of 3 fair- to poor-quality studies with small sample sizes and 2 of the 3 studies having limited follow-up. The clinical impact for patients with CSA, especially those with heart failure, remains uncertain. While results suggest a statistically significant reduction in apnea-hypopnea index (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, patient 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.

In a meta-analysis, Wang et al. (2023) evaluated the efficacy of PNS in patients with CSA. A literature search was done using PubMed, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), Scopus, and Web of Science databases. The search returned three RCTs and seven observational studies which totaled 580 patients. Overall, the authors found the scores for AHI, CAI and Arousal Index were notably reduced following PNS, but no remarkable differences in either ESS or T90. While PNS appears to have a positive impact in patients with CSA, the authors suggest additional RCTs are needed to assess long-term outcomes for the procedure; limitations included low number of RCTs available for analysis.

An updated 2021 ECRI clinical evidence assessment on the remedē System focused on the safety and efficacy for treating patients with moderate to severe CSA. The available evidence suggests transvenous phrenic nerve stimulation (TPNS) with remedē improves sleep quality and quality of life (QOL) in patients with moderate to severe CSA for up to five years. The literature consisted of 1 systematic review (SR), 3 publications of 1 RCT, and 1 pre-/post-treatment study. The systematic review consisted of five studies that compared the severity of apnea patients with active remedē implants against controls. The RCT compared a change in apnea severity by collecting AHI scores over a 5-year period along with conducting patient global assessments and daytime sleepiness in patients with active remedē implants against controls that received inactive remedē implants; however, after six months the study was no longer considered an RCT due to the permission of patients in the control arm to cross over to active stimulation. The pre-/post-treatment study reported apnea severity, daytime sleepiness, QOL, deaths, and AEs in 57 patients with moderate to severe CSA that were treated with remedē system. Limitations included high risk of bias in the SR due to small sample size, single center focus and subjective outcomes in the unblinded patients; risk of bias in the RCT due to reporting of subjective measures; and small sample size along with lack of controls for the pre-/post-treatment study. Additional studies that compare remedē with

alternative treatment options and long-term outcomes to assess and compare the system's safety and efficacy are needed.

Potratz et al. (2021) conducted a prospective case series of 24 patients with heart failure (HF) and CSA diagnosed by polysomnography. They evaluated polysomnography (to determine hypoxemic burden), echocardiography and a standardized 6-min walk test prior to device implantation (baseline) and after 6 months of follow-up. The results showed the 6-min walk distance was 369.5 ±163.5 m at baseline and significantly improved during follow-up (to 410 ±169.7 m). Hypoxemic burden determined based on time with oxygen saturation < 90% improved from 81 ±55.8 min at baseline to 27.9 ±42.8 min 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 patients with HF. The study is however limited by lack of comparison group. Although the findings are promising, the clinical benefits of PNS therapy in this patient population needs to be determined in a large, randomized controlled study with robust and objective clinical endpoints, including mortality.

In a Post Approval Study (PAS) to the remedē System Pivotal Trial (Costanzo et al., 2016), Costanzo et al. (2021) collected clinical evidence addressing long-term safety and efficacy through five years following the placement of the remedē implant which supplied transvenous phrenic nerve stimulation (TPNS). Fifty-two out of the original 151 participants took part to the five-year visit. Clinical data was collected for AHI, central-apnea index (CAI), arousal index, oxygen desaturation index, and sleep architecture. The median ESS for participants at baseline was 9 and dropped to 6 by the five-year visit demonstrating a clinically meaningful reduction; AHI and CAI showed similar results for improvement. Severe adverse effects (SAEs) were minimal and included one lead dislocation, two stimulation lead component failures and one implant infection. The authors suggest TPNS delivered with remedē is safe and effective resulting in improved sleep for patients. Limitations included lack of control group, lack of data availability for a large proportion of initial participants, which could have led to an underestimation of SAEs.

In a 2020 systematic review and meta-analysis, Voigt et al. compared the outcomes of therapies for patients with CSA and heart failure (HF) with reduced ejection fraction (REF). Nineteen randomized studies were identified that met the inclusion criteria of AHI ≥ 10, predominant CSA, and heart failure with reduced ejection fraction (HFrEF) ≤ 50%. Most trials examined adaptive servo ventilation (ASV) (8 studies) and continuous positive airway pressure (CPAP) (9 studies). The author identified only one randomized controlled trial for transvenous phrenic nerve stimulation (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 Hayes report above) conducted an analysis of all 96 patients 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, Epworth Sleepiness Scale, patient global assessment health-related quality of life, Minnesota Living with Heart Failure Questionnaire (MLHFQ), and echocardiographic parameters are reported. Heart Failure (HF) hospitalization, cardiovascular death, and the composite of HF hospitalization or cardiovascular death within 6 months were reported by the original randomized group assignment for safety assessment. Sleep metrics and quality of life improved from baseline to 6 and 12 months. At 12 months, MLHFQ scores changed by -6.8 ±20.0. The 6-month rate of HF hospitalization was 4.7% in treatment patients and 17.0% in control patients. Reported adverse events were as expected for a transvenous implantable system. The authors concluded that phrenic nerve stimulation reduces CSA severity in patients with HF. In parallel, this CSA treatment was associated with benefits on HF quality of life. These findings are limited by the lack of comparison group undergoing a different treatment.

In a manufacturer sponsored, prospective, multicenter randomized clinical trial, Costanzo, et al. (2016, included in Hayes report above) sought to evaluate the safety and effectiveness of unilateral neurostimulation in patients with central sleep apnea. Patients were recruited from 31 hospital-based centers in Germany, Poland, and the USA. Participants had to have been medically stable for at least 30 days, have received appropriate guideline recommended therapy, be aged at least 18 years, be expected to tolerate study procedures, and willing and able to comply with study requirements. Eligible patients with an AHI of at least 20 events per hour, tested by a polysomnography, underwent device implantation, and were randomly assigned by a computer-generated method to either stimulation (treatment) or no stimulation (control) for 6 months. The primary effectiveness endpoint in the intention-to-treat population was the comparison of the proportions of patients in the treatment versus control groups achieving a 50% or greater AHI reduction from baseline to 6 months, measured by a full-night polysomnography assessed by masked investigators in a core laboratory. The primary safety endpoint of 12-month freedom from serious adverse events related to the procedure, system, or therapy was evaluated in all patients. 151 eligible patients were randomly assigned to the treatment or control groups. In the analysis of results, significantly more patients in the treatment group had an AHI reduction from baseline of 50% or greater at 6 months (51%), as compared to the control group (11%; difference between groups 41%, 95% CI 25–54, p < 0.0001). 138 of 151 patients 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. 27 of 73 patients in the treatment group reported non-serious therapy-related discomfort that was resolved with simple system reprogramming in 26 patients but was unresolved in one patient. According to the authors, this study shows that transvenous neurostimulation can significantly reduce the severity of central sleep apnea and concluded it may be a promising therapeutic approach. Further research is needed to determine the clinical relevance of these findings. One of the study limitations was that patients and physicians were aware of treatment assignment, which could have introduced biases. Lack of long-term follow up and a relatively small sample size are other limitations of this study.

Laser-Assisted Uvulopalatoplasty (LAUP)

There is insufficient quality evidence to conclude LAUP is effective for obstructive sleep apnea treatment therefore, additional research involving larger, well-designed studies is needed to establish its safety and efficacy.

Shiffman et al. (2021) evaluated twenty-seven patients diagnosed with OSA and the effectiveness of the minimally invasive outpatient LAUP procedure (NightLase® LAUP) in reducing apnea–hypopnea index (AHI). Participants were treated with a dual-wavelength laser system which integrates both Nd:YAG and Er:YAG laser wavelengths. AHI was measured before the first treatment and again after the third laser treatment and these were obtained by either a home sleep or in lab sleep study prior to receiving treatment. Following the series of three treatment sessions, initial AHI values were compared to post-treatment scores. Efficacy was determined with more than 50% improvement of the AHI score. Pre-procedure AHI measurements were between 6 and 60. Based on initial AHI measurements, 26% of patients were classified as having mild OSA, 37% as moderate and 37% as severe OSA. After the treatment, 50% or more improvement was seen in 78% of the patients. As far as percent of patients improved, the greatest improvement was seen in the mild OSA group (4 out of 7 patients) but taking into account only > 50% improvement in AHI, the highest efficacy was observed in the severe OSA group. The authors' conclusion was minimally invasive LAUP using a combination of Er:YAG and Nd:YAG is a safe and effective approach for treating sleep disordered breathing, however further studies are needed to further evaluate the efficacy of the procedure and its place for treating OSA. Limitations included one single endpoint, small sample size and lack of long-term results.

Wischhusen et al. (2019) conducted a systematic review on the complications and side effects of LAUP for the treatment of snoring and OSA. Forty two articles comprised of 3093 patients, with a mean follow up of 16 months were included. Complications and side effects included bleeding, candidiasis, dehiscence, dryness, dysgeusia, dysosmia, globus sensation, surgical site infection (SSI), and velopharyngeal (VP) insufficiency stenosis. The results showed an average of 256 complications per 1,000 procedures performed, the most common being globus, dryness and VP insufficiency. The authors concluded that the LAUP procedure is associated with a high number if complications, therefore it should only be performed with caution in select patients using a tissue sparing technique or be avoided completely.

Camacho et al. (2017) performed a systematic review and meta-analysis to evaluate the use of laser-assisted uvulopalatoplasty (LAUP) alone as a treatment for obstructive sleep apnea (OSA) in adults. Twenty-three adult studies including 717 patients were selected for review. Individual patient data analyses demonstrate a 23% success rate (≥ 50% reduction in apnea-hypopnea index (AHI) and < 20 events/hr.) and an 8% cure rate. Additionally, 44% of patients had worsening of their AHI after LAUP. In this meta-analysis, LAUP reduced AHI by 32% among all patients, while the LSAT only changed minimally. There are three important points to note in this review: First, LAUP can potentially worsen obstructive sleep apnea. Second, primary snoring patients who no longer snore after LAUP should be tested for OSA post-operatively if they develop signs and symptoms of OSA. Third, given that reflexogenic dilation of the pharyngeal airway is at least partially mediated by pharyngeal mucosa afferent nerve fibers, it is possible that by destroying the surface of the soft palate with a laser, that there may be blunting of the reflexogenic dilation of the pharyngeal airway. The authors conclude that LAUP should be performed with caution or not performed at all given the unfavorable results of currently published studies. Limitations in this review are that most studies were case series studies, and only two were randomized controlled trials.

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 of minimally invasive base of tongue procedures for OSA in adults. Inclusion criteria were studies of adults who received isolated tongue base surgery as an isolated procedure and including lingual suspension, tongue base radiofrequency, submucosal minimally invasive lingual excision (SMILE), transoral robotic surgery (TORS) and tongue base ablation to treat OSAS or

snoring. Complications were classified as mild, moderate, or severe. A total of 20 studies comprised of 542 patients met the inclusion criteria. The results showed a mild complication rate of 4.65%, moderate 6.42% and 1.77% severe, 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%. With regard to 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 patient selection, surgical technique, and evaluation methodology) of included studies prevents strong conclusions.

Hsin et al. (2022) evaluated the safety and efficacy of transoral tongue suspension (TOTS) in patients with OSA. This was a case series on twenty-four patients, primarily males, with tongue obstruction. Inclusion criteria consisted of patients 18 to 65 years of age, a BMI < 32 kg/m^2 , AHI > 15/hour, mouth opening space ≥ 4 cm, tongue obstruction discovered during drug-induced sleep endoscopy, completed Epworth Sleepiness Scale, and polysomnography before and 6 months after surgery. All patients received the TOTS procedure alongside UPPP. The TOTS procedure is a new technique which takes a sublabial approach to perform 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 less invasive and a success rate of 62.5%; the authors concluded TOTS could be used as an alternative in tongue-obstructed, CPAP-failed OSA patients. Limitations include small sample size, lack of comparison groups, 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 uvulopalatopharyngoplasty (UPPP) in obstructive sleep apnea. Seven studies met the eligibility criteria, mostly case series or observational studies comparing two different TBS techniques. Four of seven studies (62 patients) used the Repose® system, and three studies (51 patients) used the modified TBS technique. The success rates were higher in the studies that used the modified technique (74.5%) versus those that used the Repose® (25.8%) system. Ten studies which included 300 patients met the eligibility criteria for TBS combined with UPPP. Seven of ten studies included 176 patients which used the Repose® system, and three studies included 124 patients which 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 of 413 patients were compared, the modified TBS technique was found to be associated with significantly higher success rates. The authors found the evidence supported primarily grade C recommendation for the benefits of both techniques with or without UPPP, but none of the results were convincing enough to provide an answer to the question of which TBS technique is most effective and safe for patients with hypopharyngeal obstruction especially in the tongue base. Limitation of the included studies was lack of comparison with other established approaches to OSA treatment.

Handler et al. (2014) performed a systematic review of suture-based tongue suspension procedures as a stand-alone therapy for hypopharyngeal obstruction in OSA. The review also compared outcomes of tongue suspension as part of various multilevel approaches to OSA surgery. Studies published after 1997 were included and involved four cohorts: tongue suspension alone, tongue suspension with UPPP, tongue suspension with genioglossus advancement (GA) plus UPPP and tongue suspension with genioglossus advancement with hyoid suspension (GAHM) plus UPPP. Twenty-seven studies were included. Six studies qualified for the tongue suspension-alone group with a surgical success rate of 36.6%. Eight studies qualified for the cohort of tongue suspension with UPPP with a surgical success rate of 62.3%. Eighteen studies qualified for the remaining two cohorts: GA plus UPPP and GAHM plus UPPP. The surgical success rates for both were 61.1%. Surgical outcomes were similar among the various combined procedures. Author noted limitations include the inability to measure statistical significance due to lack of patient demographic data for the individual studies. Secondly, of the studies used to create the surgical cohorts, three were level 2 evidence, while the remaining 24 were considered level 4 evidence. Lastly, some studies used pre- and postoperative respiratory distress index (RDI), while others used the AHI, making comparisons difficult. The findings are limited by the lack of comparison with established approaches to OSA treatment. (Authors Kuhnel 2005, Miller 2002, DeRowe 2000 and Woodson 2000 which were previously cited in this policy, are included in the Handler (2014) systematic review).

In a multicenter, prospective case series, Woodson et al. (2010) assessed the safety and effectiveness of an adjustable lingual suspension device (Advance System) for treating OSA. Forty-two surgically naive patients with moderate to severe OSA and tongue base obstruction underwent surgical insertion of a midline tissue anchor into the posterior tongue and connected to an adjustable mandibular bone anchor with a flexible tether. Outcomes included changes in AHI, sleepiness, sleep-related quality-of-life, snoring, swallowing, speech, and pain. After six months, all patients noted improvement for AHI, sleepiness, and sleep-related quality of life. Post implant pain scores were mild to moderate at day one and resolved

by day five. Device related adverse events included wound infection (7%) and edema or seroma (5%), which resolved. However, in 31 percent of patients, asymptomatic tissue anchor barb fractures were observed radiographically. The tissue anchor failure rate of the tested device precludes its clinical use. Further investigation is warranted. The findings of this case series are limited by the lack of comparison group.

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

Van Tassal et al. (2023) evaluated surgical outcomes of thirty-nine patients 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 lower than 20 with a 50% or greater decline in AHI on the postoperative sleep study. Inclusion criteria consisted of 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. Patients who had not had a previous UPPP underwent combined modified UPPP and hyomandibular suspension at the time of surgery. Patients who had previously received a UPPP underwent hyomandibular suspension alone. Polysomnography or home sleep study was completed between three- and nine-months following surgery. Success was achieved in thirty patients with a mean AHI reduction from 42.0 to 10.8. Five patients experienced procedure-related complications which included tonsillar bleed or bleed, submental seromas at submental incision site, and infection. The authors concluded adjustable hyomandibular suspension is an effective treatment when combined with modified UPPP to treat patients with moderate-to severe OSA. Limitations included small sample size, lack of control or comparison groups, and lack of long-term outcomes; future studies are warranted.

In a non-randomized study, Shaikh et al. (2022) evaluated hyoid suspension to thyroid cartilage as both an isolated and multilevel surgery approach. Inclusion criteria consisted of adult patients with OSA which was confirmed by polysomnography (PSG), intolerant of CPAP (or unwilling to try CPAP) and underwent hyoid suspension to thyroid cartilage. All individuals in the study had a preoperative PSG along with BMI and ESS scores; postoperatively additional PSG was performed along with reassessment of BMI and calculation of AHI and ESS. Surgical success was seen in 18 out of 60 patients and defined as a 50% reduction in the preop AHI along with a postoperative AHI < 20. The authors found improvement in the mean ESS from a preop 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 severe OSA individuals with improvement from 55.4 ±23.4 to 40.9 ±23.8. In addition, the obese BMI group had positive changes with improvement in AHI from 40.0 ±26.1 to 32.4 ±23.8. Complications occurred in two patients; one patient developed a 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 hyoid suspension to thyroid cartilage was successful for individuals with OSA, but particularly effective in the obese patient subset. Limitations included incomplete preop and postop home sleep study data, lack of comparison groups and loss to follow-up. Future high-quality studies are warranted.

In a product brief, ECRI (2019) identified the Encore System (used during the Airlift™ procedure) as “a minimally invasive reversible surgery intended to suspend and reposition the tongue’s anterior base and the hyoid bone to the mandible bone using bone screws and suspension sutures.” Based on one retrospective case series which evaluated nineteen individuals, the evidence was considered inconclusive.

Ong et al. (2017, included in the ECRI report above) evaluated a subset (n = 13) of nineteen individuals with severe OSA that underwent hyoid myotomy and suspension (HMS) surgery with the Airlift (Encore Medical, Inc.) procedure. Results demonstrated AHI improved from 49.9 ±16.6 events/hour preoperatively to 29.1 ±24.9 events/hour postoperatively, however the ESS showed no changes. The authors concluded HMS appears to be a valid option for improvement of OSA severity, however limitations were numerous including small sample size, no control group, no randomization, no comparisons, and 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 including PubMed/ MEDLINE, Embase, Google Scholar, Scopus, The 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 patients for review. Overall, the authors found an improvement in the AHI score by 38% along with improvement in the ESS score. The authors performed sub analyses based on primary versus secondary hyoid surgery and both appeared successful.

The authors noted the primary surgery was more successful than the secondary, with a 46.8% versus 35.2% reduction in AHI, respectively. In conclusion the authors found hyoid surgery to reduce OSA severity, but also noted additional high-quality studies are needed to further validate these findings. Limitations included small sample sizes, differences in hypopnea scoring between institutions, lack of comparison groups, and 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 and found inadequate published peer-reviewed literature to evaluate its efficacy when done alone for OSA.

Palatal Implants

Palatal implants consist of three small woven polyester or similar inserts that are placed in the soft palate to stiffen the palate and thereby reduce the number of episodes of partial or complete blockage of breathing during sleep. Pillar® and Elevo® are trade names using this technology. The woven consistency of the polyester inserts is designed to facilitate an inflammatory response that results in the formation of a fibrous capsule surrounding each insert which stiffens the palate and reduce snoring (Berry, 2015).There is insufficient evidence to conclude palatal implants are effective for obstructive sleep apnea treatment. Additional research involving larger, randomized control trials is needed to establish their safety, efficacy, and long-term outcomes.

Choi et al. (2013) performed a meta-analysis of studies evaluating the efficacy of the Pillar implant for treating mild to moderate OSA. Seven studies were included: 5 case series (n = 287) and 2 controlled trials (n = 76). Mean follow-up duration ranged from 3 to 29 months. The Pillar implant significantly reduced the Epworth Sleepiness Scale and the AHI compared to pre-procedure values. The authors concluded that the Pillar implant has a moderate effect on mild to moderate OSA but acknowledged that most of the relevant studies were case series and not placebo controlled. Most studies were also limited by short-term follow-up.

In a randomized, double-blind, placebo-controlled trial (n = 22), Maurer et al. (2012) assessed the effects of palatal implants in patients with mild to moderate sleep apnea due to palatal obstruction. Respiratory parameters and sleep efficiency (evaluated by polysomnography), snoring (evaluated by the bed partner) and daytime sleepiness (evaluated by ESS) were assessed before and 90 days after surgery. The AHI, hypopnea index (HI) and lowest oxygen saturation (LSAT) showed statistically significant improvement in the treatment group. Snoring as rated by bed partners also showed statistically significant improvement within the treatment group. There was no statistical difference when comparing the means of the treatment group with the placebo group. There was no peri- or postoperative complications and no extrusions during the follow-up period. The authors concluded that the study supports the idea that palatal implants lead to a reduction in respiratory events in patients with mild to moderate OSA, although a statistically significant superiority of palatal implants over placebo could not be demonstrated in this trial. In addition, the significance of this study is limited by the small sample size.

Gillespie et al. (2011) conducted a small RCT on fifty-one patients with mild to moderate sleep apnea to determine if the Pillar palatal implant system could decrease CPAP pressures which in turn would lead to higher patient compliance and satisfaction with CPAP therapy. The participants received a preloaded delivery system that contained either the pillar implant (active treatment) or no implant (sham). Physicians inserting the implant were instructed to not inspect the inside of the device once the preloaded cartridge had been discharged; no major adverse determinations were noted. Primary outcome assessment was CPAP pressures and collected by a smartcard device at 30, 60 and 90 days postimplant procedure. Secondary outcomes included Functional Outcome of Sleep Questionnaire (FOSQ), the Epworth Sleepiness Scale (ESS), and a 10-cm visual analog scale (VAS) for CPAP satisfaction with 0 indicating no satisfaction and 10 indicating complete satisfaction. The study failed to identify between-group differences in the changes in CPAP pressure or in adherence to treatment over time. The authors found while the active treatment group did have a slight improvement in CPAP satisfaction compared to the sham group, it was unclear as to why. The findings did not support the use of pillar implants to aid in the treatment for improved CPAP compliance.

Friedman et al. (2008, reviewed in the Choi systematic review reported above) performed a double-blinded, placebo-controlled RCT that enrolled 62 patients with mild-to-moderate OSA who underwent palatal implantation (Treatment Group, n = 31) or mock implantation (Control Group, n = 31). In the patients who completed 3 months of follow-up, mean AHI scores had decreased from 24 to 16 points for the Treatment Group versus an increase from 20 to 21 (14) points for the Control Group. Although improvements were statistically significant, they were relatively small. Furthermore, the study was limited by short follow-up.

In a multi-institution, double-blind, placebo-controlled study, Steward et al. (2008, reviewed in the Choi systematic review reported above) randomly assigned one hundred patients with mild to moderate OSA and suspected retropalatal obstruction to treatment with three palatal implants or sham placebo. Palate implants demonstrated efficacy over placebo for several important outcome measures with minimal morbidity, but overall effectiveness remained limited. The investigators concluded that further study is needed.

In a retrospective, case series, Friedman et al. (2006a) evaluated the Pillar implant system alone and in combination with other procedures for treatment of mild-to-moderate OSA/hypopnea syndrome (OSAHS). A total of 125 patients who had mild-to-moderate OSAHS were assigned to palatal implantation alone (Palatal Group, n = 29), or in combination with other procedures. The authors report an "objective cure rate" of 34%. The study is limited by lack of comparison group receiving treatments other than the Pillar implant system.

Walker et al. (2006, reviewed in the Choi systematic review reported above) studied the Pillar implant system in 53 patients in a 90-day multicenter noncomparative study. Inclusion criteria were OSA caused by palatal obstruction, an AHI score of 10 to 30, a BMI less than or equal to 32 kg/m^2, age greater than or equal to 18 years, and a soft palate of sufficient length for the implants. Mean AHI score decreased from 25.0 at baseline to 22 at 90 days follow-up. Although this decrease was small, it was statistically significant ($p = 0.05$). These findings were limited by lack of comparison group receiving established OSA treatments.

Three other small, uncontrolled studies have been performed to evaluate the Pillar Palatal Implant System for mild-to moderate OSA. These studies enrolled 16 to 26 patients who had an AHI score of 5 to 30. These studies reported that, compared with baseline, patients obtained small-to-moderate but statistically significant improvements in outcomes such as AHI and Epworth Sleepiness Scale (ESS) scores at up to 1 year of follow-up; however, these studies do not provide reliable evidence of efficacy since they did not involve any control or comparison groups (Friedman, 2006b; Goessler, 2007, reviewed in the Choi systematic review reported above; Nordgard, 2007).

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 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)

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 patients 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.

Lechien et al. (2021) conducted a systematic review and meta-analysis evaluating outcomes of transoral robotic surgery (TORS) for base of tongue reduction in obstructive sleep apnea syndrome (OSAS). Outcomes measured were changes over time in AHI, changes over time in daytime sleepiness (scored by ESS), changes in lowest O_2 saturation levels, and surgical success rate. There were 1,690 patients included in the review. The overall summary estimates showed the reduction of AHI was 24.25, reduction of ESS was 7.92, increase of lowest 0_2 saturation was 6.04%, and overall surgical success was 69%. The authors note many weaknesses within the analysis which limited the capacity to make definitive conclusions including the profile of patients requiring TORS BOT reduction differing across studies (selection bias), surgical techniques differed amongst studies which may impact the reliability of the conclusions, and discrepancies in 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 patients may have been included in more than one study. The authors suggest improved methodology of future studies by recommending the comparison of future studies through use of similar and standardized criteria and definitions. (Lee et al. (2012) and Friedman et al. (2012) which were 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 that of other alternative procedures such as coblation tongue base resection (CTBR), upper airway stimulation (UAS), radiofrequency, CO_2 laser, and endoscopic partial midline glossectomy (EPMG). Clinical outcomes assessed were AHI, O_2 saturation and ESS score. While the authors found all the procedures significantly reduced AHI and ESS scores along with increase in O_2 saturation, no significant differences between the surgical procedures were found in operation time, in success rates or complication rates; the success rate of TORS was no more effective than that of the other compared alternative procedures. Limitations of analysis included lack of RCTs, lack of long-term outcomes, comparison to non-established approaches, and the retrospective design of most of the included studies.

Lan et al. (2019, included in Tsou and Chang (2020) and Lechien (2021) systematic reviews cited above) retrospectively compared the efficacy of trans-oral robotic surgery (TORS) with that of coblation assisted tongue base reduction surgery in patients with obstructive sleep apnea syndrome (OSAS). Thirty-three cases were analyzed; sixteen received TORS and seventeen received coblation surgery. Both groups received concomitant uvulopalatoplasty, and surgical outcomes were evaluated by comparing the initial polysomnography results with a follow-up PSG within at least 3 months after the surgery. ESS and complications were also utilized in the comparison between the two groups. The authors found no difference in the success rate between the two procedures. Limitations were this 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 utilized for TORS. The authors concluded surgical performance in combination with

uvulopalatoplasty is an effective approach for OSAS, however future randomized controlled trials are needed to evaluate the efficacy of TORS.

Miller et al. (2017) conducted systematic review and meta-analysis on the effect of transoral robotic surgery (TORS) base of tongue (BOT) reduction sleep-related outcomes in patients with obstructive sleep apnea (OSA). Studies on TORS BOT reduction as part of OSA treatment in adult patients with pre- and postoperative apnea-hypopnea index (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 patients met inclusion criteria. Pooled analyses (baseline vs. post-surgery) showed significant improvement in the following: AHI (44.3 ±22.4 to 17.8 ±16.5, p < .01), ESS (12.9 ±5.4 to 5.8 ±3.7, p < .01), lowest oxygen saturation (79.0 ±9.5 to 84.1 ±6.5, p < .01), and snoring visual analog scale (9.3 ±0.8 to 2.4 ±2.43, p < .01). Surgical success rate was 68.4%. Cure rate was 23.8%. The authors concluded TORS BOT is considered successful in the majority of adult patients with OSA, however further studies must be performed to optimize patient selection criteria to achieve higher rates of success. The findings are however limited by lack of 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) which were previously cited in this policy are included in this meta-analysis).

Justin et al. (2016) conducted a systematic review of the literature evaluating the effectiveness, complications, and safety of TORS for the treatment of OSA. Sixteen studies were included. Three of these studies were case series with comparison to historical controls and the other were case series without comparison group. TORS was almost always combined with other sleep surgery procedures. The summary estimate of the decrease in 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 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 patients. However, the morbidity may be greater than 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 lack of concurrent comparison group in the included studies. (Lee et al. (2012), Friedman et al. (2012) and Vicini et al. (2010) which were previously cited in this policy are included in this meta-analysis).

Distraction Osteogenesis for Maxillary Expansion (DOME)

There is insufficient quality evidence to conclude DOME is effective for the treatment of adult OSA. The published literature lacks randomized control trials needed to establish the safety, efficacy, and long-term outcomes. Future studies including comparison groups are warranted.

In a retrospective case series, 75 patients with a diagnosis of OSA intolerant of CPAP along with 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 3-D cone-beam computed tomography (CBCT) and placed with mini-screws. The expander device was activated 5 to 7 days postop 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 Epworth Sleepiness Scale (ESS) and Nasal Obstruction Symptom Evaluation (NOSE) questionnaires before to and during the 3-to-6-month postop period. The participants 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 the results showed significant improvements in alleviating nasal obstruction, decreasing AHI, and improving the amount of REM sleep. Limitations of the study included 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 that underwent DOME by assessing subjective and objective outcomes. The patients included in the study were intolerant to CPAP, had no hypertrophy of either the lingual or palatine tonsils, had class 3 or 4 Mallampati and a suffered a narrow palatal arch. The procedure was performed with application of the maxillary expander with fixation of 4 to 6 screws to the midpalate and maxillary bone and then performance of LeFort I maxillary osteotomy. Postoperatively the patients were taught to turn the expander daily for the next five weeks. NOSE and ESS scores were obtained for evaluation. The authors found that DOME procedure widened the maxilla and therefore was deemed successful by improvement of the NOSE and ESS scores. Limitations included lack of 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 for a case series of 20 patients. Each patient underwent pre- and post-DOME polysomnographies along with outcome measurements from ESS, NOSE rhinomanometry and CT measurements of the nasal floor. Following the surgical procedure, significant decline was noted in all the measurements along with airflow resistance and it was concluded that the DOME procedure was successful at widening the maxilla in all

the adult patients with OSA. However, limitations included lack of 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 considers Uvulopalatopharyngoplasty (UPPP) 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.” (AAO-HNS website; revised April 2021).

The AAO-HNS considers upper airway stimulation (UAS) 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 and intolerant or unable to achieve benefit with positive pressure therapy. (AAO-HNS website; revised November 2019).

An AAO-HNS position statement 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 (OSAHS) and with moderate to severe OSAHS with evidence of tongue base or associated hypopharyngeal obstruction. Results weaken in obese patients; therefore, this procedure has a weaker recommendation for this population.(AAO-HNS website; 2016).

An AAO-HNS position statement for treatment of OSA 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.” (AAO-HNS website; 2010; revised 2021).

An AAO-HNS position statement on tongue based procedures states that genioglossus advancement and hyoid myotomy/suspension, whether performed separately or combined, are considered effective and non-investigational with proven clinical results when considered as part of the comprehensive surgical management of symptomatic adult patients with mild obstructive sleep apnea (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.

American Academy of Sleep Medicine (AASM)

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

- Uvulopalatopharyngoplasty (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 positive airway pressure (PAP) therapy, while those with moderate OSA should initially be offered either PAP therapy or oral appliances. The clinical evidence for UPPP is very low quality (Option recommendation – either inconclusive or conflicting evidence or conflicting expert opinion). This recommendation is a change from the previous practice parameter.
- Maxillomandibular Advancement (MMA) Surgery: MMA is indicated for 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 mild and moderate OSA patients, have been considered and found ineffective or undesirable. Although the clinical evidence is 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).
- Multi-Level or Stepwise Surgery (MLS): Multi-level 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 positive airway pressure therapy, or in whom oral appliances have been considered and found ineffective or undesirable. The clinical evidence for RFA is 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

secondary outcomes. Some studies actually saw worsening of the overall AHI. The clinical evidence for LAUP is low quality. (Standard recommendation – generally accepted patient-care strategy).
- Palatal Implants: Palatal implants may be effective in some patients with mild obstructive sleep apnea who cannot tolerate or who are unwilling to adhere to positive airway pressure 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 2016) recommends the following for treatment of central sleep apnea syndrome (CSAS) related to CHF:
- Recommendation 1: Adaptive servo-ventilation (ASV) targeted to normalize the apnea-hypopnea index (AHI) should not be used for the treatment of CSAS related to CHF in adults with an ejection fraction ≤ 45% and moderate or severe CSA predominant, sleep-disordered breathing. (STANDARD AGAINST).
- Recommendation 2: Adaptive servo-ventilation (ASV) targeted to normalize the apnea-hypopnea index (AHI) can be used for the treatment of CSAS related to CHF in adults with an ejection fraction > 45% or mild CHF 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 hypoglossal nerve stimulation (HNS) should not be used as first-line treatment for OSA patients in general. However, the panel suggest that HNS compared to no treatment should be considered as a salvage treatment in patients with symptomatic OSA, who cannot be sufficiently treated with CPAP, BiPAP or MAD and an AHI < 50events/hour.
- Based on very low-quality evidence, in adult patients with OSA, the panel suggests using either MMO or CPAP.

National Institute for Health and Care Excellence (NICE)

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

A NICE guideline states that current evidence on soft-palate implants for obstructive sleep apnea (OSA) raises no major safety concerns, but there is inadequate evidence that the procedure is efficacious in the treatment of this potentially serious condition for which other treatments exist. Therefore, soft-palate implants should not be used in the treatment of OSA (NICE, 2007).

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 obstructive sleep apnea (apnea-hypopnea index < 30 per hour), suggest offering mandibular advancement devices, fabricated by a qualified dental provider, as an alternative to positive airway pressure therapy. (Weak)
- For patients with obstructive sleep apnea with an apnea-hypopnea index of 15 – 65 per hour and a body mass index < 32 kg/m^2 who cannot adhere to positive airway pressure therapy, suggest evaluation for surgical treatment with hypoglossal nerve stimulation therapy. (Weak)
- For patients with severe obstructive sleep apnea who cannot tolerate or are not appropriate candidates for other recommended therapies, suggest evaluation for alternative treatment with maxillomandibular advancement 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 OSA are regulated by the FDA, but products are too numerous to list. Refer to the following website for more information (use product codes LRK or LQZ). Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 29, 2024)

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 with a non-supine AHI < 20. It records position and movement to assess changes in position on sleep quality. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID= K180608. (Accessed August 29, 2024)

Bongo, manufactured by InnoMed Healthscience, Inc., received 510(k) approval (K180619) from the FDA on August 16, 2018. The device is an intranasal appliance indicated for use in the treatment of mild to moderate obstructive sleep apnea (OSA) in adults > 66 lbs. Refer to the following website for additional information: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180619.pdf. (Accessed August 29, 2024)

Radiofrequency ablation (RFA) systems for surgery are regulated by the FDA as Class II devices, and a large number of these RFA systems have been approved via the 510(k) process. The following devices are among the RFA devices specifically approved for coagulation of tissues in the head and neck.

- The Somnoplasty™ System, manufactured by Olympus (formerly Gyrus ENT), received 510(k) approval (K982717) from the FDA on November 2, 1998. Intended for the reduction of the incidence of airway obstructions in patients suffering from upper airway resistance syndrome (URAS) or obstructive sleep apnea syndrome (OSAS), the system generates heat for creating finely controlled lesions at precise locations within the upper airway. As the tissue heals, it reduces tissue volume, opening the airway. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/K982717.pdf. (Accessed August 29, 2024)
- ArthroCare ENT Coblator Surgery System, manufactured by ArthroCare ENT, received 510(k) approval (K030108) from the FDA on February 3, 2003. The system is a bipolar, high frequency electrosurgical system indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery. Using low temperatures, the technology destroys tissue using radiofrequency energy to excite electrolytes in a conductive medium, such as saline. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K030108.pdf. (Accessed August 29, 2024)

The eXciteOSA device (DEN200018) is a removable tongue muscle stimulation device that delivers neuromuscular stimulation to the tongue in order to reduce snoring and mild obstructive sleep apnea (AHI < 15) for patients that are 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 August 29, 2024)

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. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID= K191320. (Accessed August 29, 2024)

The remedē® System, manufactured by Zoll, is an implantable phrenic nerve stimulator indicated for the treatment of moderate to severe central sleep apnea (CSA) in adult patients that received FDA approval on October 6, 2017. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id= P160039. (Accessed August 29, 2024)

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 pre-threaded suture. It is also suitable for the performance of a hyoid procedure. It is indicated for the treatment of OSA and/or snoring. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/K981677.pdf. (Accessed August 29, 2024)

The Pillar™ Palatal Implant System for treating obstructive sleep apnea, manufactured by Medtronic ENT, received 510(k) approval (K040417) from the FDA on July 28, 2004. The system of palatal implants is intended to stiffen the soft palate tissue, which may reduce the incidence of upper airway obstruction in patients suffering from mild to moderate OSA. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/K040417.pdf. (Accessed August 29, 2024)

The FDA granted premarket approval (PMA) on April 30, 2014, to the Inspire® Upper Airway Stimulation (UAS) system (Inspire Medical Systems Inc.) (P130008). It is intended for treatment of patients with an AHI ≥ 20 and ≤ 65. On June 8, 2023, the FDA expanded the indications (P130008s090) for the Inspire UAS system in OSA patients with an AHI lower limit of ≤ 15, an upper limit baseline AHI from 65 to 100 and the upper limited BMI from 32 to 40. The system is used in adults who have been confirmed to fail 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. Information available at:

- 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 February 14, 2025)

On March 20, 2023, the FDA expanded coverage of the Inspire® Upper Airway Stimulation system (P130008/S089) to pediatric patients ages 13 to 18 years with Down syndrome and severe OSA (AHI of ≥ 10 and ≤ 50) and who do not have complete concentric collapse at the soft palate level; contraindicated for or not effectively treated by adenotonsillectomy; confirmation of failure, or cannot tolerate PAP therapy despite attempts to improve compliance, and have followed standard of care in considering all other alternative/adjunct therapies.
Information available at:
https://www.fda.gov/medical-devices/recently-approved-devices/inspire-upper-airway-stimulation-p130008s089.
(Accessed August 29, 2024)

The device is also referred to as the Inspire II Information available at:
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id= P130008
- https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008C.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008D.pdf

(Accessed August 29, 2024)

In March of 2023, the FDA issued a safety concern regarding jaw remodeling devices for adults. Further information can be found at the following website: https://www.fda.gov/medical-devices/safety-communications/evaluation-safety-concerns-certain-dental-devices-used-adults-fda-safety-communication. (Accessed September 10, 2024)

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Policy History/Revision Information

Date	Summary of Changes
09/01/2025	**Coverage Rationale** ***Surgical Treatment*** • Added notation to indicate polysomnography should be repeated if there has been clinically significant weight loss or gain, changes in cardiovascular disease, or there are persistent or recurrent symptoms since the last study • Revised coverage criteria for: Uvulopalatopharyngoplasty (UPPP), Mandibular Osteotomy (MO), and Maxillomandibular Osteotomy and Advancement (MMA) in an Adult Patient ○ Replaced criterion requiring "*diagnosis of* moderate to severe Obstructive Sleep Apnea (OSA) [Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 1]" with "moderate to severe OSA [Apnea Hypopnea Index (AHI) ≥ *15* or Respiratory Disturbance Index (RDI) ≥ 15] *as determined by Polysomnography (Attended)*" Implantable Hypoglossal Nerve Stimulation with a U.S. Food and Drug Administration (FDA) Approved Device in Adolescents Aged 10-18 Years with Down Syndrome ○ Replaced criterion requiring "diagnosis of severe OSA (as determined by a *Polysomnogram within 24 months* and an AHI ≥ 10 and RDI ≤ 50 events per hour)" with "diagnosis of severe OSA [as determined by *Polysomnography (Attended)* and an AHI ≥ 10 and RDI ≤ 50 events per hour]" **Definitions** • Added definition of "Respiratory Disturbance Index (RDI)" **Applicable Codes** • Added CPT/HCPCS codes 0964T, 0965T, 0966T, and E0490 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information • Archived previous policy version 2025T0525RR

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates.

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