Obstructive and Central Sleep Apnea Treatment (for Indiana Only)

Policy Number: CS116IN.14
Effective Date: March 1, 2024

Ü Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Indiana Only)

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

Non-Surgical Treatment

Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) under certain circumstances. 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.

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 repositioning devices (e.g., Slow Wave)
- Morning repositioning device
- Epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime Appliance)]

Surgical Treatment

The following surgical procedures are proven and medically necessary for treating OSA as documented by polysomnography. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:

- Maxillomandibular Advancement
- Osteotomy, Anterior Segment, Mandible
- Uvulopalatopharyngoplasty (UPPP)

If medical necessity cannot be determined using these criteria, refer to the InterQual® Medicare: Procedures, Surgical Treatment of Obstructive Sleep Apnea (OSA).

Click here to view the InterQual® criteria.

Implantable hypoglossal nerve stimulation is medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® Medicare: Procedures, Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea.

Click here to view the InterQual® criteria

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.

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)

Definitions

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, 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).

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..

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).

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 federal, state, or contractual requirements 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
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

CPT Code	Description
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
93152	Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
93153	Interrogation without programming of implanted phrenic nerve stimulator system

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
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

HCPCS Code	Description
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)

Note: Codes labeled with an asterisk (*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana.

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's 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).

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 times 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 to sleep in the supine position.

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.

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.

Implantable hypoglossal nerve stimulation systems are ways to relieve upper airway obstruction. There are two hypoglossal nerve stimulation devices: The Inspire® Upper Airway Stimulation device (Inspire Medical) and the aura6000™ Sleep Therapy System (ImThera Medical). The Inspire device treats moderate to severe OSA and is designed for use in individuals who are unable or unwilling to use a CPAP device. Inspire's construction and implantation are comparable to those of a pacemaker: a surgeon implants the device containing a neurostimulator subcutaneously in the individual's chest with one lead attached to the individual's hypoglossal nerve (cranial nerve XII) at the base of the tongue and one lead implanted in the individual's chest. The lead in the chest consists of a pressure sensor that detects breathing. Information about respiration rate is relayed to the device, which stimulates the hypoglossal nerve in the tongue. When stimulated, the tongue moves forward, thus opening the airway. The individual can operate the device by remote control, which the individual activates before going to sleep. The device turns on after 20 minutes to minimize disrupting the individual's sleep onset; the device turns off via remote when the individual wakes.

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 (e.g., Bongo Rx)

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.

Sleeper et al. (2022) conducted a laboratory comparison to assess the expiratory pressures generated by the following four expiratory positive airway pressure (EPAP) devices: ULTepap, Provent, Bongo Rx, and Theravent. Measurement of the expiratory and inspiratory pressures were captured by a Respironics digital pressure manometer. Prior to the measurement of each of the devices, the manometer was calibrated to zero. The authors found the expiratory pressures generated by ULTepap and Provent were similar, with ULTepap being slightly lower at all flow rates. The Bongo Rx and Theravent devices produced substantially lower backpressures than Provent and ULTepap, in addition to Bongo Rx having a significantly lower flow rate. In summary, the authors felt not all FDA cleared EPAP devices provide similar mechanical results and additional clinical trials comparing short- and long-term efficacy, patient satisfaction, and adherence are warranted. Limitations included lack of OSA-specific outcomes and lack of clinical evidence of efficacy.

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.

In a multicenter, prospective study, Rosenthal et al. (2009) evaluated the efficacy of the Provent nasal device, for the treatment of OSA and evaluated adherence to the device over a 30-day in-home trial period. Participants (n = 34) with a baseline apnea-hypopnea index (AHI) ≥ 5 were evaluated. Treatment was well tolerated and accepted by the participants. The authors documented an overall reduction in AHI; however, therapeutic response was variable (and at times inconsistent) among the participants. Further research is required to identify the ideal candidates for this new therapeutic option in the management of OSA. Lack of comparison group limits the validity of the study. A potential for bias exists due to manufacturer sponsorship of the study.

Colrain et al. (2008) conducted a pilot study to test the hypothesis that the application of expiratory resistance via a nasal valve device would improve breathing during sleep in subjects with OSA and in primary snorers. Thirty men and women were recruited for the study. Twenty-four had at least mild OSA (AHI > 5), and 6 were primary snorers. Subjects underwent 2 nights of

polysomnographic evaluation, one with and one without a new nasal resistance device with the order of nights counterbalanced across participants. The device consisted of a small valve inserted into each nostril calibrated to provide negligible inspiratory resistance but increased expiratory resistance. Standard polysomnography was conducted to compare participants' sleep both with and without the device, with the scoring conducted blind to treatment condition. The apnea-hypopnea (AHI) and oxygen desaturation (O2DI) indices both significantly decreased, and the percentage of the night spent above 90% saturation significantly increased with device use. The results of this pilot study are suggestive of a therapeutic effect of expiratory nasal resistance for some OSA patients and indicate that this technique is worthy of further clinical study. The findings are limited by lack of comparison group and lack of comparison to standard treatment for OSA. A potential for bias exists due to manufacturer sponsorship of the study.

Several clinical trials which address EPAP devices are ongoing; refer to: https://www.clinicaltrials.gov/ct2/home.

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 prefabricated oral appliance or device is limited; there is little evidence to demonstrate the safety or efficacy of these devices in their use for OSA.

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 nonsurgical 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 which 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 obstructive sleep apnea (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.

Kotecha et al. (2021, included in the ECRI report and Moffa systematic review above) assessed objective snoring and respiratory parameters on a case series of 70 patients with the novel eXciteOSA device. Inclusion criteria consisted of adults 18 years and older suffering from habitual snoring for greater than 6 months along with a live-in partner. Each participant received the eXciteOSA® with an explanation of how to use the device. The daily therapy of 20 minutes over 6 weeks consisted of a series of pulse bursts with intensity controlled to a tolerable level by patient. The primary outcome measure was to have a reduction in snoring. Epworth Sleepiness Score (ESS) was completed on all patients before and after the use of the device along with respiratory parameters (AHI, ODI and oxygen saturations). VAS was also obtained from the patient's partner. The mean AHI value was 5.94/h which dropped to 5.37/h following completion of eXciteOSA® device therapy. In addition, the ODI reduced from 4.92 to 4.73 post treatment. The authors concluded the device appears to be safe for patients with snoring and mild sleep apnea and could be a preferred option for patients. However, the study lacked a control group, lacked standard snoring parameters, addressed a small sample size, and lacked long-term outcomes.

Baptista et al. (2021, included in the ECRI report and Moffa systematic review above) evaluated daytime neuromuscular electrical training (NMES) of tongue muscles in patients suffering from mild sleep apnea and snoring. 115 participants over the age of 18 years, AHI < 15 and had a live-in partner were included in the study; 73 were male and 42 were female with an average mean age of 46 years. For two weeks prior to the study, the live-in partner was to rate their partner's snoring using the VAS; in addition, both the partner and participant completed sleep quality questionnaires, including the Pittsburgh Sleep Quality Index (PSQI) and ESS at the end of the two-week period. At the start of the study each participant was given the eXciteOSA device and instructed on its use. Participants were asked to use the device 20 minutes once/day for a total of 6 weeks; they were to record daily assessments of any side effects and adverse events. Patient compliance with the therapy was validated remotely via the smartphone application. The mean AHI reduced from 6.85 to 5.03, and the ODI from 5.68 to 4.33. 90% of patients demonstrated some reduction in their objective snoring time and the VAS scores for bed partners showed a significant reduction in their perception of their partner's snoring. No severe adverse events were noted, and the main side effect reported for 15% of the patients was oral pooling of their saliva. The authors concluded the eXciteOSA device was well tolerated with a significant reduction in AHI. Limitations were acknowledged by the authors which included the need for randomization and comparison, restriction in duration and follow-up of the study, and lack of long-term outcomes.

Clinical trials which address the eXciteOSA device along with its safety and efficacy are ongoing; refer to: https://www.clinicaltrials.gov/ct2/home.

Mandibular 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 unproven.

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. Research shows that 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 website; 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 website; 2010; revised 2021).

American Academy of Sleep Medicine (AASM)

The AASM Clinical Practice Guideline 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

AASM practice parameters on the treatment of central sleep apnea do not list oral appliances as a treatment option (Aurora et al., 2012).

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 nonsurgical or surgical therapies.”

In a 2014 consensus paper, the AADSM describes the purpose, function, and physical features of an effective oral appliance. It identifies an effective oral appliance as a custom-fabricated, FDA approved device which is designed to maintain airway patency during sleep for the management of OSA (AADSM, 2018). It further states a sleep-related breathing disorder such as OSA should be diagnosed by a physician and then referred to a dentist for oral appliance therapy.

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 suggest that CPAP be used versus custom made dual block mandibular advancement device (MAD)
- Based on low-quality evidence, the panel suggest 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 suggest using CPAP instead of myofunctional therapy for adult patients with OSA
- Based on a very low certainty of evidence, the panel suggest 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 suggest either vibrational positional therapy or custom made dual-block MAD be used

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

The remedē system (ZOLL® Medical Corporation) is an implantable device intended to treat adults with moderate to severe CSA (Hayes 2022). 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 2023 Hayes technology assessment concluded there is very-low-quality body of evidence evaluating the use of phrenic nerve stimulation (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.

Abraham et al. (2015, included in Hayes report above) conducted a small (57 patients) prospective, multicenter, case series pilot study to evaluate chronic, transvenous, unilateral phrenic nerve stimulation to treat CSA using the implantable Respicardia remedē System. Results showed improvement in AHI, central apnea index, arousals, sleep efficiency, and rapid eye movement sleep after 3 months of treatment. These improvements were sustained at 6 months and were accompanied by alleviation of both sleepiness and heart failure symptoms. The author's conclusion was that transvenous, unilateral phrenic nerve stimulation appears safe and effective for treating CSA, but as the study was limited by its size, the lack of a parallel control arm, and the diversity of the patient population, they recommended that findings should be confirmed in a prospective, randomized, controlled trial.

The TREAT-CSA Study is a study registered in clinicaltrials.gov in 2015 that was terminated in 2017 (NCT02577445). It was designed as a cohort study comparing approximately 300 participants with or without implantation of the remedé® system to treat sleep-disordered breathing. The study appears to have been terminated after recruitment of 31 participants. Results reported on clinicaltrials.gov show that among the 17 participants implanted with the remedé® system, there were 6 (35%) severe adverse events, including cardiac decompensation, cardiac arrest, other cardiac disorders, lead dislocation, and acute renal failure. None of the 14 participants without implantation of the remedé® system developed severe adverse events. The clinicaltrials.gov entry also reports 4 (23%) other (not including serious) adverse events among the 17 participants with implantation of the remedé® system, while none of the participants without implantation of the remedé® system developed such adverse events.

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.

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.

Lin et al. (2006) conducted a prospective, controlled trial in which they evaluated LAUP as treatment for moderately severe or severe OSA in 25 subjects. After LAUP, impedance in non-responders remained elevated, but impedance in responders returned to levels comparable to those in the 15 healthy controls.

An RCT conducted by Larrosa et al. (2004, included in the Camacho systematic review) focused primarily on LAUP for treatment of snoring; however, it included some patients with mild OSA and evaluated outcomes other than snoring intensity. Patients were randomized to LAUP or a placebo surgery control group. This study was small (n = 25) and did not involve any follow-up after the post treatment assessment at 3 months; however, it found that there were no statistically significant differences between the control group and LAUP treatment group in snoring, daytime sleepiness, apnea-hypopnea index, or QOL measures. A shortcoming of the trial is that patients underwent only one LAUP treatment rather than the multiple treatments provided by Terris and Ferguson (refer below).

Ferguson et al. (2003, included in the Camacho systematic review) conducted a small RCT (n = 45) with 8 months of follow-up to evaluate LAUP versus no treatment for mild OSA. Although patients who underwent an average of 2.4 LAUP procedures had statistically significant improvements in snoring and apnea-hypopnea index relative to the control group, improvements in daytime sleepiness and sleep apnea QOL scores were not statistically significant. Moreover, the benefits were limited, corresponding to a 44% decrease in mean snoring intensity and 35% decrease in apnea-hypopnea index.

Terris et al. (2002) also conducted a randomized trial of LAUP but used a randomized crossover design in which patients were randomly assigned to LAUP or RFA of the palate and then allowed to undergo the non-assigned treatment if their assigned treatment did not provide adequate improvement. Although this study was small (n = 17) and involved only 16 weeks of follow-up, the results suggest that multiple LAUP and RFA treatments of the palate reduce snoring but do not significantly reduce the other symptoms of sleep-disordered breathing such as daytime sleepiness or upper airway collapse.

Lysdahl et al. (2002) compared the outcomes of 121 patients treated for bronchopathy, the majority of whom also reported apneas. Sixty-one were treated with uvulopalatopharyngoplasty and 60 with laser-assisted uvulopalatoplasty. The patients were requested to assess the frequency of symptoms associated with OSA prior to surgery, at 3-month follow up and 5 to 8 years postoperatively. Both groups reported significant improvements; however, UPPP was superior to LAUP in terms of all clinical effect parameters. However, the surgeries are not directly comparable as more tissue is removed in UPPP, and the OSA was self-reported.

Lingual Suspension/Tongue Fixation

No studies on the long-term success of this procedure are available, and there is little quality clinical data to demonstrate its efficacy.

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.

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/m2 , 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 subanalyses 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.

Bowen et al. (2005) examined the efficacy of hyoid myotomy and suspension as a treatment in patients with OSA. Twenty-nine male patients previously treated with non-surgical methods underwent hyoid suspension. Six males had mild OSA, 9 had moderate OSA, 14 had severe OSA and all reported excessive daytime sleepiness and were heavy snorers. Success was measured by an AHI lower than 20, 50% or greater decline in AHI, and no oxygen desaturations below 85% on the patient’s postop sleep study. Secondary outcomes included daytime sleepiness as defined by ESS and the severity of snoring. After review of the data, the authors concluded poor results were found; only five patients achieved a successful outcome. Limitations included small sample size, 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

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.

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).

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/m2, 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

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.

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.

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).

Franklin et al. (2009) conducted a systematic review evaluating the efficacy (randomized controlled trials only) and adverse effects (including observational studies) of surgery for OSA. The authors reported that only a small number of randomized controlled trials with a limited number of patients assessing some surgical modalities for sleep apnea are available. For RFA, the studies reviewed did not support any benefit on daytime sleepiness, apnea reduction or quality of life. Furthermore, several persistent adverse effects were detected.

In a pilot randomized study, RFTVR of palate and uvula was compared to radiofrequency channeling (Bassiouny, 2007). The authors concluded that their preliminary findings “confirms the favorable effects of radiofrequency in the treatment of patients with snoring and mild to moderate obstructive sleep apnea (OSA) particularly on snoring.”

Hofmann et al. (2006) compared temperature controlled RFTVR to conventional surgery using a non-randomized comparative (cohort study) design. Both UPPP and RFTVR reduced snoring, but UPPP led to improvement in AHI and HI, while RFTVR did not. While postoperative pain was shorter in duration for RFTVR, the number of treatments was higher, leading to a comparable length of postoperative pain.

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. The published literature is limited by lack of comparison group and therefore high risk of bias. 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 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 January 2019).

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 (2016) position statement recommends tongue-based suspension as effective and even comparable to genioglossus advancement when considered as part of a comprehensive approach in symptomatic adult patients with OSA and adult patients with moderate to severe OSA. (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).

American Academy of Sleep Medicine (AASM)

In a clinical guideline for the evaluation, management and long-term care of adults diagnosed with OSA, members of the AASM task force point to weight loss as a recommendation for overweight OSA patients and that it be combined with other treatments for overall success (Epstein et al, 2009).

The AASM recommends surgery as a treatment option for OSA when noninvasive treatments such as CPAP or oral appliances have been unsuccessful. The use of hypoglossal nerve stimulation is not addressed as a therapeutic option (Aurora, 2010a).

A 2010 AASM practice parameter (Aurora, 2010a; Aurora, 2010b; Caples, 2010) on surgical options for OSA 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 recommends surgery as a treatment option for OSA when noninvasive treatments such as CPAP or oral appliances have been unsuccessful; and one of the most common surgical methods is the uvulopalatopharyngoplasty procedure. (AASM website; accessed June 25, 2021).

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)

Sleep Foundation

The Sleep Foundation suggests surgery is rarely a first line form of treatment for OSA. Surgery is to be considered when treatments such as CPAP or oral appliance therapy have been unsuccessful. (Sleep Foundation website; accessed June 8, 2022).

American Sleep Apnea Association (ASAA)

The ASAA position is that while positive airway pressure therapy is the first line of treatment for moderate to severe sleep apnea, patient compliance represents a problem. For the noncompliant patient, surgery may be a feasible alternative. The surgeon must first determine what part of the upper airway is causing the obstruction to airflow. The sites of obstruction could be anywhere in the upper respiratory tract including the nose, tongue, and throat.

It considers that there are many surgical options for the treatment of sleep apnea for patients who cannot tolerate CPAP therapy. Because the airway pattern and the severity of obstruction vary greatly between individuals, the surgical regimen must be catered to a particular individual. Often it takes a combination of procedures to achieve success. A logical stepwise approach must be taken when a patient seeks surgery, and it is a requisite that the patient finds a surgeon who understands both the pathophysiology of sleep apnea and the anatomy of the upper respiratory tract to ensure the best chance of success (ASAA, 2015).

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 suggest 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 suggest using either MMO or CPAP

ERS published a review for additional new therapies which were explored, and the GRADE system used to assess the quality of evidence and the strength of recommendations (Verbraecken et al, 2021). The final recommendation concluded that maxillo-mandibular osteotomy had overall certainty of evidence to be low to very low but could be used to benchmark quality of care for people with OSA across Europe and to improve outcomes.

Agency for Healthcare Research and Quality (AHRQ)

A comparative effectiveness report for 2011 from the Agency for Healthcare Research and Quality (AHRQ) conducted a systematic review of the evidence on OSA diagnosis and treatment in adults. The report made the following conclusions:

- The strength of evidence is high that AHI is an independent predictor of CPAP compliance
- The strength of evidence is moderate that the Epworth Sleepiness Scale is an independent predictor of CPAP compliance
- The strength of evidence is moderate to show that the use of mandibular advancement devices (MAD) improves sleep apnea signs and symptoms
- The strength of evidence is moderate that CPAP is superior to MAD in improving sleep study measures
- The strength of evidence is insufficient to determine the relative merits of surgical treatments versus CPAP
- The strength of evidence is insufficient regarding the relative merit of MAD versus surgery in the treatment of OSA

Limitations in the evidence review included lack of trials evaluating long-term clinical outcomes, the strength of evidence, and publication bias.

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/m2 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). Information available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 17, 2023)

The Lunoa System (NightBalance BV) received 510(k) Premarket Notification (K180608) from the FDA on June 5, 2018. Information available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K180608. (Accessed August 17, 2023)

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. Information available at: https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180619.pdf. (Accessed August 17, 2023)

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. Information available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/K982717.pdf
- Coblation® technology, 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. Information available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K030108.pdf (Accessed August 17, 2023)

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). Information available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200018. (Accessed August 17, 2023)

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. Information available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K191320. (Accessed August 17, 2023)

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. Information available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160039. (Accessed August 17, 2023)

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. Information available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/K981677.pdf. (Accessed August 17, 2023)

The Pillar® 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. Information available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/K040417.pdf. (Accessed August 17, 2023)

The FDA granted premarket approval (PMA) on April 30, 2014, to the Inspire Upper Airway Stimulation (UAS) system (Inspire Medical Systems Inc.) (P130008), which includes the Model 3024 Implantable Pulse Generator, the Model 4063 Stimulation Lead, the Model 4323 Sensing Lead, the Model 2740 Physician Programmer, and the Model 3032 Patient Programmer for treatment of patients with an AHI ≥ 20 and ≤ 65. On June 8, 20323, the FDA expanded the indications (P130008s090) for the Inspire UAS system in OSA patients with 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 such as CPAP or BPAP machines, and who do not have a complete concentric collapse at the soft palate level.

PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as: inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night); or unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it). 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

(Accessed August 21, 2023)

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 21, 2023)

The device is also referred to as the Inspire II (search MNQ in the Product Code field at: 510(k) Premarket Notification Database). 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 21, 2023)

Additional Product Information

- Advance System (Aspire Medical) is an adjustable tongue base suspension system that is not yet FDA approved for marketing in the U.S.
- Aura6000 (ImThera Medical) is an implantable hypoglossal nerve stimulation system that is not yet FDA approved for marketing in the U.S.

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Policy History/Revision Information

Date	Summary of Changes
05/01/2024	**Related Policies** • Removed reference link to the Medical Policy titled *Orthognathic (Jaw) Surgery (for Indiana Only)* (retired May. 1, 2024)
03/01/2024	**Coverage Rationale** ***Non-Surgical Treatment*** • Revised list of unproven and not medically necessary devices; added "epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime appliance)] ***Surgical Treatment*** • Replaced language indicating "the [listed] surgical procedures are proven and medically necessary for treating OSA as documented by polysomnography *in certain circumstances*" with "the [listed] surgical procedures are proven and medically necessary for treating OSA as documented by polysomnography" • Revised list of unproven and not medically necessary surgical procedures; added: o Isolated hyoid myotomy o Stand-alone uvulectomy • Added notation to clarify the list of unproven and not medically surgical procedures is not all inclusive

Date	Summary of Changes
	Definitions • Added definition of "Body Mass Index (BMI)" • Removed definition of: o Advanced Practice Providers (APPs) o Respiratory Disturbance Index (RDI) **Applicable Codes** • Added CPT code 42140 • Removed CPT codes 64553, 64568, and 64569 • Revised description for HCPCS code K1028 • Added notation to indicate CPT/HCPCS codes 42140 and A7049 are not managed for medical necessity review for the State of Indiana at this time; refer to the most current *Prior Authorization and Notification List* for UnitedHealthcare Community Plan of Indiana • Removed notation indicating HCPCS code E0486 is not managed for medical necessity review for the state of Indiana at this time **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS116IN.13

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.