Obstructive Sleep Apnea Treatment (for Louisiana Only)

Policy Number: CS116LA.X
Effective Date: July 1, 2021

Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Nonsurgical Treatment

Removable oral appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., polysomnography or Home Sleep Apnea Testing).

For many individuals, oral appliance therapy (OAT) may be an effective alternative to failed continuous positive airway pressure (CPAP) therapy. Documentation of the following is required:

- A patient presenting with symptoms of OSA be seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine prior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019)
- A treating physician (MD or DO) must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019)
- If the patient refuses CPAP therapy, documentation of the refusal from the patient's treating physician (MD or DO) must be supplied

For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, Medicare: Durable Medical Equipment, Oral Appliances for Obstructive Sleep Apnea.

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 Obstructive Sleep Apnea (OSA)
- Nasal dilator devices for treating OSA
- Removable oral appliances for treating central sleep Apnea

Surgical Treatment

The following surgical procedures are proven and medically necessary for treating Obstructive Sleep Apnea as documented by polysomnography. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures:

- Maxillomandibular Advancement
- Osteotomy, Anterior Segment, Mandible
- Osteotomy, LeFort I
- Osteotomy, Sagittal Split, Mandible Ramus
- Uvulopalatopharyngoplasty (UPPP)

Click here to view the InterQual® criteria.

Implantable hypoglossal nerve stimulation is proven and medically necessary in an adult patient with moderate to severe OSA when all of the following criteria are met:

- Body mass index of (BMI) less than or equal to 32kg/m^2; and
- Apnea Hypopnea Index (AHI) of 15 or greater and less than or equal to 65 as determined with polysomnography; and
- Absence of complete concentric collapse at the soft palate level; and
- Failure or intolerance of Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines)
    - 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)

The following surgical procedures are unproven and not medically necessary for treating Obstructive Sleep Apnea due to insufficient evidence of efficacy:

- Laser-assisted uvulopalatoplasty (LAUP)
- Lingual suspension – Also referred to as tongue stabilization, tongue stitch or tongue fixation
- Palatal implants
- Radiofrequency ablation of the soft palate and/or tongue base
- Transoral robotic surgery (TORS)

Definitions

Apnea: The cessation of airflow (≥90% decrease in airflow compared to baseline) lasting at least 10 seconds. Apneas are classified as obstructive, mixed, or central based on the pattern of respiratory effort. An obstructive Apnea is associated with continued or increased inspiratory effort throughout the entire period of absent airflow. A central Apnea is associated with absent inspiratory effort throughout the entire period of absent airflow. Mixed Apneas are associated with absent inspiratory effort in the initial portion of the event, followed by resumption of inspiratory effort in the second portion of the event (AASM Scoring Manual, 2020).

Apnea Hypopnea Index (AHI): The number of Apneas plus the number of hypopneas, times 60, divided by total sleep time (AASM Scoring Manual, 2020).

Home Sleep Apnea Testing: 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). Also referred to as out-of-center sleep testing or portable monitoring.

Hypopnea: An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or the event is associated with an arousal (AASM Scoring Manual, 2020).

Obstructive Sleep Apnea: The American Academy of Sleep Medicine (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/hr

Physician: Any Doctor of Medicine or Doctor of Osteopathy who is properly licensed and qualified by law.

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

Respiratory Disturbance Index (RDI): The number of Apneas plus the number of Hypopneas plus the number of Respiratory Effort-Related Arousals, times 60, divided by total sleep time (AASM Scoring Manual, 2020).

Respiratory Effort-Related Arousal (RERA): A sequence of breaths characterized by increasing respiratory effort, inspiratory flattening in the nasal pressure or PAP device flow channel or an increase in end-tidal PCO2 (children) leading to an arousal from sleep. Respiratory effort-related arousals do not meet criteria for Hypopnea and have a minimum duration of at least 10 seconds in adults or the duration of at least two breaths in children (AASM Scoring Manual, 2020).

Respiratory Event Index (REI): Total number of respiratory events scored, times 60, divided by monitoring time. The REI is used for Home Sleep Apnea Testing (AASM Scoring Manual, 2020).

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.

CPT Code	Description
0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)
0467T	Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator
0468T	Removal of chest wall respiratory sensor electrode or electrode array
21199	Osteotomy, mandible, segmental; with genioglossus advancement
21206	Osteotomy, maxilla, segmental (e.g., Wassmund or Schuchard)
21685	Hyoid myotomy and suspension
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
42145	Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)
42299	Unlisted procedure, palate, uvula
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator

CPT Code	Description
64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator

HCPCS Code	Description
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment
K1001	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
S2080	Laser-assisted uvulopalatoplasty (LAUP)
S2900	Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)

Description of Services

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

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, oral appliance therapy, electrostimulation devices and surgery. Positive airway pressure therapy may use any one of the following techniques: continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP), bi-level 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.

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

A nasal dilator is a removable appliance that is placed just inside the nostril and is secured in place with hypoallergenic adhesive. Using small valves, the device increases pressure inside the nose by creating resistance during exhalation to maintain an open airway during sleep (Theravent website).

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 include but are not limited to vibrating devices, pillows, tennis balls, and chest vests that prevent the patient to sleep in the supine position.

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

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

Nonsurgical 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 research brief, Hayes (2020) identifies enough published evidence to evaluate the use of the Lunoa system (NightBalance) for positional OSA. The review identified fourteen abstracts including RCTs, a prospective comparison study and multiple prospective uncontrolled studies. The findings were conflicting and thus conclusions regarding this technology cannot be made.

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.

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.

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). 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.

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.

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.

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 OSA patients 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 devices 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 and. 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 OSA patients 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 pre-specified 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, a novel device placed in the nares that imposes an expiratory resistance 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.

Professional Societies

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 Obstructive Sleep Apnea (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 College of Physicians (ACP)

The 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 report on non-CPAP therapies for OSA concluded that nasal dilators cannot be recommended as effective treatments for OSA (Randerath et al., 2011).

Surgical Treatment

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

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

In a Cochrane review, Sundaram and Lasserson (2005; reviewed 2008) evaluated surgical treatment for obstructive sleep apnea. Ten studies (602 participants) of mixed quality met the inclusion criteria. Data from eight studies were eligible for assessment in the review. No data could be pooled. The authors concluded that there are now a small number of trials assessing different surgical techniques with inactive and active control treatments. The studies assembled in the review do not provide evidence to support the use of surgery in sleep apnea/hypopnea syndrome, as overall significant benefit has not been demonstrated. The participants recruited to the studies had mixed levels of AHI but tended to suffer from moderate daytime sleepiness where this was measured. Short-term outcomes are unlikely to consistently identify suitable candidates for surgery. Long-term follow-up of patients who undergo surgical correction of upper airway obstruction is required. This would help to determine whether surgery is a curative intervention, or whether there is a tendency for the signs and symptoms of sleep apnea to re-assert themselves, prompting patients to seek further treatment for sleep apnea.

Hypoglossal Nerve Stimulation

In a product brief by ECRI (2020), evidence from four retrospective observational studies suggest that Inspire works better than surgery for improving sleep and reducing OSA symptoms. Future controlled studies that provide long-term data are needed to validate Inspire benefits and compare it against CPAP therapy.

A Hayes report concluded that the overall quality of the evidence evaluating hypoglossal nerve stimulation for treating OSA is very low. However, evidence does suggest that the intervention is relatively safe and may reduce the severity of OSA and improve PROMs (excessive daytime sleepiness, function, quality of life) for patients with OSA that have failed or are intolerant to

CPAP therapy. Stimulation of the hypoglossal nerve may provide a treatment option for patients with moderate-to-severe OSA for whom CPAP has failed to provide relief, but the procedure may carry risks for complications and postimplantation surgical procedures. Additional good-quality comparative studies with larger sample sizes are needed to define the patient population that is most likely to respond to this therapy option (Hayes, 2016. Updated 2019).

A National Institute for Health and Care Excellence (NICE) guideline 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).

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

The Stimulation Therapy for Apnea Reduction (STAR) trial (Strollo et al. 2014, included in the Hayes and ECRI reports) evaluated the clinical safety and effectiveness of upper airway stimulation at 12 months for the treatment of moderate to severe obstructive sleep apnea. Using a multicenter, prospective case series design, an upper airway stimulation device was surgically implanted in patients with obstructive sleep apnea who had difficulty either accepting or adhering to CPAP therapy. The primary outcome measures were the apnea-hypopnea index (AHI; the number of apnea or hypopnea events per hour, with a score of ≥15 indicating moderate-to-severe apnea) and the oxygen desaturation index (ODI; the number of times per hour of sleep that the blood oxygen level drops by ≥4 percentage points from baseline). Secondary outcome measures were the Epworth Sleepiness Scale, the Functional Outcomes of Sleep Questionnaire (FOSQ), and the percentage of sleep time with the oxygen saturation less than 90%. The study included 126 participants; 83% were men. The mean age was 54.5 years, and the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 28.4. The median AHI score at 12 months decreased 68%, from 29.3 events per hour to 9.0 events per hour; the ODI score decreased 70%, from 25.4 events per hour to 7.4 events per hour. Secondary outcome measures showed a reduction in the effects of sleep apnea and improved quality of life. In the randomized phase, the mean AHI score did not differ significantly from the 12-month score in the nonrandomized phase among the 23 participants in the therapy-maintenance group (8.9 and 7.2 events per hour, respectively); the AHI score was significantly higher (indicating more severe apnea) among the 23 participants in the therapy-withdrawal group (25.8 vs. 7.6 events per hour). The ODI results followed a similar pattern. The rate of procedure-related serious adverse events was less than 2%. The authors concluded that upper airway stimulation led to significant improvements in objective and subjective measurements of the severity of obstructive sleep apnea. The lack of a control group limits the validity of the results of this study. This study was funded by Inspire Medical Systems.

Follow-up studies of the same patient population at 18 and 36 months, indicate that the treatment effects are maintained over time. Limitations are the same as the original study (Strollo et al., 2015; Woodson et al., 2016).

In a subgroup analysis of the STAR trial, Woodson et al. (2014, included in the Hayes and ECRI reports) assessed the efficacy and durability of upper airway stimulation via the hypoglossal nerve on obstructive sleep apnea (OSA) severity including objective and subjective clinical outcome measures. The study included a consecutive cohort of 46 responders at 12 months from a prospective phase III trial of 126 implanted participants. Participants were randomized to either therapy maintenance ("ON") group or therapy withdrawal ("OFF") group for a minimum of 1 week. Short-term withdrawal effect as well as durability at 18 months of primary (apnea hypopnea index and oxygen desaturation index) and secondary outcomes (arousal index, oxygen desaturation metrics, Epworth Sleepiness Scale, Functional Outcomes of Sleep Questionnaire, snoring, and blood pressure) were assessed. Both the therapy withdrawal group and the maintenance group demonstrated significant improvements in outcomes at 12 months compared to study baseline. In the randomized assessment, therapy withdrawal group returned to baseline, and therapy maintenance group demonstrated no change. At 18 months with therapy on in both groups, all objective respiratory and subjective outcome measures showed sustained improvement similar to those observed at 12 months. The authors concluded that withdrawal of therapeutic upper airway stimulation results in worsening of both objective and subjective measures of sleep and breathing, which when resumed results in sustained effect at 18 months. The authors state that

reduction of obstructive sleep apnea severity and improvement of quality of life were attributed directly to the effects of the electrical stimulation of the hypoglossal nerve. The author-reported limitations of this study include the selection bias of only including responders to upper airway stimulation device therapy and the lack of subject or investigator blinding. This study was funded by Inspire Medical Systems.

Laser-Assisted Uvulopalatoplasty (LAUP)

There is insufficient 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.

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. Individual data demonstrated a success rate of 23%, cure rate of 8%, and worsening of the AHI among 44% of patients. There are three important points to note in this review: First, laser-assisted uvulopalatoplasty (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 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.

Two of the reviewed studies were randomized trials that evaluated LAUP. 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 nonassigned 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 rhonchopathy, 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.

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 obstructive sleep apnea (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 uvulopalatopharyngoplasty (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 apnea-hypopnea index (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.

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 obstructive sleep apnea (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 apnea-hypopnea index (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 apnea-hypopnea index (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 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.

A National Institute for Health and Care Excellence (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).

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 (1 4) 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's measures with minimal morbidity, but overall effectiveness remains 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 (mean age 42 11 years) 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.

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. (Authors 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)

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.

Lan et al. (2019) 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. Epworth sleepiness scale (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 either 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. postsurgery) showed significant improvement in the following: AHI (44.3 ± 22.4 to 17.8 ± 16.5, P < .01), Epworth Sleepiness Scale (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.

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.

In a prospective, nonrandomized trial using historical controls, Lee et al. (2012, reviewed in the Miller 2017 and the Justin 2016 systematic reviews cited above) assessed the use of transoral robot-assisted lingual tonsillectomy and uvulopalatopharyngoplasty for the surgical management of tongue base obstruction in patients with obstructive sleep apnea. Twenty patients have completed the study to date. The rate of surgical success was 45%, and the rate of surgical response was 65%. The mean preoperative apnea-hypopnea index of 55.6 decreased by 56.7%, to a mean postoperative value of 24.1, and the minimum arterial oxygen saturation increased from the mean preoperative value of 75.8% to the mean postoperative value of 81.7%. The mean Epworth Sleepiness Scale score improved from 13.4 to 5.9. One patient had postoperative bleeding that required cauterization, resulting in a major complication rate of 4.2%. This study is limited by lack of randomization, comparison group, and small sample size.

Friedman et al. (2012, reviewed in the Miller 2017 and the Justin 2016 systematic reviews cited above) assessed the feasibility and efficacy of robotically assisted partial glossectomy without tracheotomy by comparing obstructive sleep apnea-hypopnea syndrome (OSAHS) outcomes with those of established techniques. Using a historical cohort study, 40 consecutive patients underwent transoral robotic surgery (TORS) for OSAHS and were followed up with regard to complications, morbidity and subjective and objective outcomes. Data from 27 of these patients who underwent concomitant z-palatoplasty with 6-month

follow-up were compared with those of 2 matched cohorts of patients who underwent either radiofrequency or coblation reduction of the tongue base and z-palatoplasty. No major bleeding or airway complications were observed. Postoperative pain and length of admission were similar between groups. All groups saw Epworth score and snore score improvement. Patients undergoing robot-assisted surgery took longer than their radiofrequency counterparts to tolerate normal diet and resume normal activity. Apnea hypopnea index (AHI) reduction averaged 60.5% ± 24.9% for TORS versus 37.0% ± 51.6% and 32.0% ± 43.3% for coblation and radiofrequency, respectively. Only the robotic group achieved statistically significant improvement in minimum oxygen saturation. Surgical cure rate for TORS (66.7%) was significant compared with radiofrequency (20.8%) but not compared with coblation (45.5%). The authors concluded that it is feasible to perform robotically assisted partial glossectomy without the need for tracheotomy. This technique resulted in greater AHI reduction, but increased morbidity compared with the other techniques studied. This study is limited by a retrospective observational design and small sample size.

Vicini et al. (2010, reviewed in the Miller 2017 and the Justin 2016 systematic reviews cited above) evaluated the feasibility, tolerability and efficacy of tongue base management using transoral robotic surgery (TORS) in patients with obstructive sleep apnea-hypopnea syndrome (OSAHS). Seventeen patients with OSAHS, principally related to tongue base hypertrophy, underwent TORS (Intuitive da Vinci®). Patients with a minimum follow-up of 3 months were evaluated. Ten patients [mean preoperative apnea-hypopnea index (AHI): 38.3 +/-23.5 SD] were included in the study. The postoperative polysomnographic results were fairly good (mean postoperative AHI: 20.6 +/- 17.3 SD), and the functional results (pain, swallowing and quality of life) were encouraging. Complications were rare and of minor importance. The authors concluded that transoral robotic tongue base management in patients with OSAHS primarily related to tongue base hypertrophy is feasible and well tolerable and that these preliminary results encouraging and worthy of further evaluation. The study is however limited by lack of comparison group and large loss to follow-up.

Professional Societies

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

No evidence-based clinical practice guidelines addressing the treatment of OSA were identified. The organization has published several position statements related to OSA treatment options; however, these documents are based on an informal process of expert or committee consensus (AAO-HNS website).

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).

American Academy of Sleep Medicine (AASM)

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).

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 step-wise approach must be taken when a patient seeks surgery, and it is a requisite that the patient find 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 report on non-CPAP therapies for OSA concluded that maxillomandibular osteotomy seemed to be as efficient as CPAP in patients who refused conservative treatment. Radiofrequency tonsil reduction, tongue base surgery, uvulopalatal flap, laser midline glossectomy, tongue suspension and genioglossus advancement cannot be recommended as single interventions. Uvulopalatopharyngoplasty, palatal implants and hyoid suspension should only be considered in selected patients and potential benefits should be weighed against the risk of long-term side-effects. Multilevel surgery is only a salvage procedure for OSA patients (Randerath et al., 2011).

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. See the following website for more information (use product codes LRK or LQZ): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 18, 2020)

The Lunoa System (NightBalance BV) received 510(k) Premarket Notification (K180608) from the FDA on June 5, 2018. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K180608. (Accessed May 27, 2020)

The PROVENT® Professional Sleep Apnea Therapy (Theravent, Inc.) received FDA approval (K090398) on April 3, 2009. The device is placed inside the nostrils and is intended for the treatment of obstructive sleep apnea. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090398.pdf. (Accessed June 18, 2020)

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

- The Somnoplasty™ System, manufactured by Olympus (formerly Gyrus ENT), received 510(k) approval (K982717) from the FDA on November 2, 1998. Intended for the reduction of the incidence of airway obstructions in patients suffering from upper airway resistance syndrome (URAS) or obstructive sleep apnea syndrome (OSAS), the system generates heat for

creating finely controlled lesions at precise locations within the upper airway. As the tissue heals, it reduces tissue volume, opening the airway. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/K982717.pdf.
- 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. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K030108.pdf.

(Accessed June 18, 2020)

The AIRvance™ Tongue Suspension system (formerly Repose™), manufactured by Medtronic ENT, received 510(k) approval (K981677) from the FDA on August 27, 1999. The system is intended for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is also suitable for the performance of a hyoid procedure. It is indicated for the treatment of OSA and/or snoring. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/K981677.pdf. (Accessed June 18, 2020)

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. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/K040417.pdf. (Accessed June 18, 2020)

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. Inspire UAS 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. The device is also referred to as the Inspire II (search MNQ in the Product Code field at: 510(k) Premarket Notification Database). The FDA mandated 2 post-approval studies: a prospective, single-arm cohort study to evaluate the long-term safety of the device in 124 subjects over 5 years, and a multicenter, prospective, single-arm cohort study to evaluate long-term safety and effectiveness of the device and effectiveness of the physician training program in 127 subjects over 5 years. 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 June 18, 2020)

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.

References

Amali A, Motiee-Langroudi M, Saedi B, et al. A comparison of uvulopalatopharyngoplasty and modified radiofrequency tissue ablation in mild to moderate obstructive sleep apnea: a randomized clinical trial. J Clin Sleep Med. 2017 Sep 15;13(9):1089-1096.

American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) website. Available at: http://www.entnet.org/sites/default/files/Guidance-Documents.pdf. Accessed June 18, 2020.

American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) website. Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA). Revised November 2019. Accessed April 23, 2020.

American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) website. Position Statement: Use of Oral Appliances for the Treatment of Obstructive Sleep Apnea (OSA). Revised November 2019. Accessed April 23, 2020.

American Academy of Sleep Medicine (AASM). AASM Style Guide for Sleep Medicine Terminology. Updated November 2015. Available at: https://aasm.org/download-free-aasm-style-guide-for-sleep-medicine-terminology/. Accessed June 10, 2020.

American Academy of Sleep Medicine (AASM). AASM Manual for the Scoring of Sleep and Associated Events: Rules, terminology and technical specifications. V2.6. January 2020.

American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM). Policy Statement on the Diagnosis and Treatment of Obstructive Sleep Apnea. December 7, 2012. Available at: https://aadsm.org/docs/jointpolicy.pdf. Accessed April 22, 2020.

American Sleep Apnea Association (ASAA). Varieties of OSA surgery. 2020. Available at: https://www.sleepapnea.org/treat/sleep-apnea-treatment-options/sleep-apnea-surgery/. Accessed April 28, 2020.

Atef A, Mosleh M, Hesham M, et al. Radiofrequency vs. laser in the management of mild to moderate obstructive sleep apnea: does the number of treatment sessions matter? J Laryngol Otol. 2005;119(11):888-893.

Aurora RN and Morgenthaler TI. On the goodness of recommendations: the changing face of practice parameters. Sleep. 2010b;33(10):1273-6.

Aurora RN, Casey KR, Kristo D, et al. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. Sleep. 2010a;33(10):1408-1413.

Aurora RN, Chowdhuri S, Ramar K, et al. The treatment of central sleep apnea syndromes in adults: practice parameters with an evidence-based literature review and meta-analyses. Sleep. 2012 Jan 1;35(1):17-40.

Baba RY, Mohan A, Metta VV, et al. Temperature controlled radiofrequency ablation at different sites for treatment of obstructive sleep apnea syndrome: a systematic review and meta-analysis. Sleep Breath. 2015 Sep;19(3):891-910.

Bassiouny A, El Salamawy A, Abd El-Tawab M, et al. Bipolar radiofrequency treatment for snoring with mild to moderate sleep apnea: a comparative study between the radiofrequency assisted uvulopalatoplasty technique and the channeling technique. Eur Arch Otorhinolaryngol. 2007 Jun;264(6):659-67.

Barnes H, Edwards BA, Joosten SA, et al. Positional modification techniques for supine obstructive sleep apnea: A systematic review and meta-analysis. *Sleep Med Rev*. 2017;36:107-115.

Berry RB, Kryger MH, Massie CA. A novel nasal expiratory positive airway pressure (EPAP) device for the treatment of obstructive sleep apnea: a randomized controlled trial. *Sleep*. 2011;34(4):479-485. Bostanci A, Turhan M. A systematic review of tongue base suspension techniques as an isolated procedure or combined with uvulopalatopharyngoplasty in obstructive sleep apnea. Eur Arch Otorhinolaryngol. 2016 Oct;273(10):2895-901.

Camacho M, Nesbitt NB, Lambert E, et al. Laser-Assisted uvulopalatoplasty for obstructive sleep apnea: a systematic review and meta-analysis. Sleep. 2017 Mar 1;40(3).

Camacho M, Malu OO, Kram YA, et al. Nasal dilators (Breathe Right Strips and NoZovent) for snoring and OSA: a systematic review and meta-analysis. Pulm Med. 2016;2016:4841310.

Caples SM, Rowley A, Prinsell JR, et al. Surgical modifications of the upper airway for obstructive sleep apnea in adults: a systematic review and meta-analysis. Sleep. 2010;33(10):1396-1407.

Certal VF, Zaghi S, Riaz M, et al. Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: A systematic review and meta-analysis. Laryngoscope. 2015 May;125(5):1254-64.

Choi JH, Kim SN, Cho JH. Efficacy of the Pillar implant in the treatment of snoring and mild-to-moderate obstructive sleep apnea: a meta-analysis. Laryngoscope. 2013 Jan;123(1):269-76.

Coblation website. Available at: http://www.smith-nephew.com/. Accessed June 18, 2020.

Colrain IM, Brooks S, Black J. A pilot evaluation of a nasal expiratory resistance device for the treatment of obstructive sleep apnea. J Clin Sleep Med. 2008 Oct 15;4(5):426-33.

DeRowe A, Gunther E, Fibbi A, et al. Tongue-base suspension with a soft tissue-to-bone anchor for obstructive sleep apnea: preliminary clinical results of a new minimally invasive technique. Otolaryngol Head Neck Surg. 2000 Jan;122(1):100-3.

de Ruiter MHT, Benoist LBL, de Vries N, et al. Durability of treatment effects of the Sleep Position Trainer versus oral appliance therapy in positional OSA: 12-month follow-up of a randomized controlled trial [published correction appears in Sleep Breath. 2018 May;22(2):451]. *Sleep Breath*. 2018;22(2):441-450.

ECRI Institute. Product Brief. Inspire II upper airway stimulation therapy (Inspire Medical Systems, Inc.) for treating obstructive sleep apnea. January 2014. Updated February 2020.

ERCI Institute. Product Brief. NightBalance Lunoa (Philips Respironics, Inc.) for Treating Positional obstructive Sleep Apnea. January 2020.Ferguson KA, Heighway K, Ruby RR. A randomized trial of laser-assisted uvulopalatoplasty in the treatment of mild obstructive sleep apnea. Am J Respir Crit Care Med. 2003;167(1):15-19.

Franklin KA, Anttila H, Axelsson S, et al. Effects and side-effects of surgery for snoring and obstructive sleep apnea–a systematic review. Sleep. 2009 Jan;32(1):27-36.

Friedman M, Hamilton C, Samuelson CG, et al. Transoral robotic glossectomy for the treatment of obstructive sleep apnea-hypopnea syndrome. Otolaryngol Head Neck Surg. 2012 May;146(5):854-62.

Friedman M, Schalch P, Joseph NJ. Palatal stiffening after failed uvulopalatopharyngoplasty with the Pillar Implant System. Laryngoscope. 2006b;116(11):1956-1961.

Friedman M, Schalch P, Lin HC, et al. Palatal implants for the treatment of snoring and obstructive sleep apnea/hypopnea syndrome. Otolaryngol Head Neck Surg. 2008;138(2):209-216.

Friedman M, Vidyasagar R, Bliznikas D, et al. Patient selection and efficacy of pillar implant technique for treatment of snoring and obstructive sleep apnea/hypopnea syndrome. Otolaryngol Head Neck Surg. 2006a;134(2):187-196.

Gao YN, Wu YC, Lin SY, et al. Short-term efficacy of minimally invasive treatments for adult obstructive sleep apnea: A systematic review and network meta-analysis of randomized controlled trials. *J Formos Med Assoc*. 2019;118(4):750–765.

Gelardi M, Intiglietta P, Porro G, et al. Internal nasal dilator in patients with obstructive sleep apnea. *Acta Biomed*. 2019;90(2-S):19–23. Published 2019 Jan 11.

Goessler UR, Hein G, Verse T, et al. Soft palate implants as a minimally invasive treatment for mild to moderate obstructive sleep apnea. Acta Otolaryngol. 2007;127(5):527-531.

Handler E, Hamans E, Goldberg AN, Mickelson S. Tongue suspension: an evidence-based review and comparison to hypopharyngeal surgery for OSA. Laryngoscope. 2014 Jan;124(1):329-36.

Hayes, Inc. Hayes Medical Technology Directory. Hypoglossal nerve stimulation for the treatment of obstructive sleep apnea. Landsdale, PA: Hayes Inc., March 2016. Updated October 2019.

Hayes, Inc. Hayes Medical Technology Directory. NightBalance (Philips) for the Treatment of Positional Obstructive Sleep Apnea. Landsdale, PA: Hayes Inc., January 2020.

Hidalgo Armas L, Turino C, Cordero-Guevara J, et al. A new postural device for the treatment of positional obstructive sleep apnea. A pilot study. *Respir Med*. 2019;151:111-117. doi:10.1016/j.rmed.2019.02.005

Hofmann T, Schwantzer G, Reckenzaun E, et al. Radiofrequency tissue volume reduction of the soft palate and UPPP in the treatment of snoring. Eur Arch Otorhinolaryngol. 2006;263(2):164-170.

Justin GA, Chang ET, Camacho M, et al. Transoral robotic surgery for obstructive sleep apnea: a systematic review and meta-analysis. Otolaryngol Head Neck Surg. 2016 May;154(5):835-46.

Kompelli AR, Ni JS, Nguyen SA,et al. The outcomes of hypoglossal nerve stimulation in the management of OSA: A systematic review and meta-analysis. World J Otorhinolaryngol Head Neck Surg. 2018 Sep 25;5(1):41-48.

Kryger MH, Berry RB, Massie CA. Long-term use of a nasal expiratory positive airway pressure (EPAP) device as a treatment for obstructive sleep apnea (OSA). J Clin Sleep Med. 2011 Oct 15;7(5):449-53B.

Kuhnel T; Schurr C; Wagner B, et al. Morphological changes of the posterior airway space after tongue base susp ension. Laryngoscope. 2005 Mar;115(3):475-80.

Kushida CA, Morgenthaler TI, Littner MR, et al. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005. Sleep. 2006 Feb 1;29(2):240-3.

Lan WC, Chang WD, Tsai MH, Tsou YA. Trans-oral robotic surgery versus coblation tongue base reduction for obstructive sleep apnea syndrome. *PeerJ*. 2019;7:e7812. Published 2019 Oct 2.

Larrosa F, Hernandez L, Morello A, et al. Laser-assisted uvulopalatoplasty for snoring: does it meet the expectations? Eur Respir J. 2004;24(1):66-70.

Lee JM, Weinstein GS, O'Malley BW Jr, et al. Transoral robot-assisted lingual tonsillectomy and uvulopalatopharyngoplasty for obstructive sleep apnea. Ann Otol Rhinol Laryngol. 2012 Oct;121(10):635-9.

Lin CC, Lee KS, Chang KC, et al. Effect of laser-assisted uvulopalatoplasty on oral airway resistance during wakefulness in obstructive sleep apnea syndrome. Eur Arch Otorhinolaryngol. 2006;263(3):241-7.

Lysdahl M, Haraldsson PO. Uvulopalatopharyngoplasty versus laser uvulopalatoplasty: prospective long-term follow-up of self-reported symptoms. Acta Otolaryngol. 2002 October 1;122(7):752-7.

Maurer JT, Sommer JU, Hein G, et al. Palatal implants in the treatment of obstructive sleep apnea: a randomised, placebo-controlled single-centre trial. Eur Arch Otorhinolaryngol. 2012 Jul;269(7):1851-6.

Medtronic website. https://www.medtronic.com/it-it/operatori-sanitari/products/ear-nose-throat/sleep-disordered-breathing/pillar-procedure-system-snoring-sleep-apnea.html. Accessed June 9, 2020.

Miller SC, Nguyen SA, Ong AA, et al. Transoral robotic base of tongue reduction for obstructive sleep apnea: A systematic review and meta-analysis. Laryngoscope. 2017 Jan;127(1):258-265.

Miller FR, Watson D, Malis D., et al. Role of the tongue base suspension suture with The Repose System bone screw in the multilevel surgical management of obstructive sleep apnea. *Otolaryngol Head Neck Surg*. 2002;126(4):392-398.

National Institute for Health and Care Excellence (NICE). IPG241. Soft-palate implants for obstructive sleep apnoea. November 2007.

National Institute for Health and Care Excellence (NICE) IPG598. Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea. November 2017.

Nordgard S, Hein G, Stene BK, et al. One-year results: palatal implants for the treatment of obstructive sleep apnea. Otolaryngol Head Neck Surg. 2007;136(5):818-822.

Patil SP, Ayappa IA, Caples SM, et al. Treatment of Adult Obstructive Sleep Apnea With Positive Airway Pressure: An American Academy of Sleep Medicine Systematic Review, Meta-Analysis, and GRADE Assessment. J Clin Sleep Med. 2019 Feb 15;15(2):335-343.

Qaseem A, Holty JE, Owens DK, et al. Management of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2013;159:471-483.

Ramar K, Dort LC, Katz SG, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. J Clin Sleep Med. 2015 Jul 15;11(7):773-827.

Randerath WJ, Verbraecken J, Andreas S, et al.; European Respiratory Society task force on non-CPAP therapies in sleep apnoea. Non-CPAP therapies in obstructive sleep apnoea. Eur Respir J. 2011 May;37(5):1000-28.

Rosenthal L, Massie CA, Dolan DC, et al. A multicenter, prospective study of a novel nasal EPAP device in the treatment of obstructive sleep apnea: efficacy and 30-day adherence. J Clin Sleep Med. 2009 Dec 15;5(6):532-7.

Rossi VA, Winter B, Rahman NM, et al. The effects of Provent on moderate to severe obstructive sleep apnoea during continuous positive airway pressure therapy withdrawal: a randomised controlled trial. Thorax. 2013 Sep;68(9):854-9.

Somnoplasty website. Available at: http://medical.olympusamerica.com/products/somnoplasty. Accessed June 10, 2020.

Srijithesh PR, Aghoram R, Goel A, et al. Positional therapy for obstructive sleep apnoea. *Cochrane Database Syst Rev*. 2019;5(5):CD010990.

Steward DL, Huntley TC, Woodson BT, et al. Palate implants for obstructive sleep apnea: multi-institution, randomized, placebo-controlled study. Otolaryngol Head Neck Surg. 2008 Oct;139(4):506-10.

Steward DL, Weaver EM, Woodson BT. A comparison of radiofrequency treatment schemes for obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg. 2004a;130(5):579-585.

Steward DL. Effectiveness of multilevel (tongue and palate) radiofrequency tissue ablation for patients with obstructive sleep apnea syndrome. Laryngoscope. 2004b;114(12):2073-2084.

Strollo PJ Jr, Gillespie MB, Soose RJ, et al.; Stimulation Therapy for Apnea Reduction (STAR) Trial Group. Upper airway stimulation for obstructive sleep apnea: durability of the treatment effect at 18 months. Sleep. 2015 Oct 1;38(10):1593-8.

Strollo PJ Jr, Soose RJ, Maurer JT, et al.; STAR Trial Group. Upper-airway stimulation for obstructive sleep apnea. N Engl J Med. 2014 Jan 9;370(2):139-49.

Sundaram S, Lim J, Lasserson TJ. Surgery for obstructive sleep apnea. Cochrane Database of Systematic Reviews 2005, Issue 4. Art. No.:CD001004. DOI: 10.1002/14651858. CD001004.pub2. Content reviewed and assessed as up-to-date July 2008. Edited with no change to conclusion 2013.

Terris DJ, Coker JF, Thomas AJ, et al. Preliminary findings from a prospective, randomized trial of two palatal operations for sleep-disordered breathing. Otolaryngol Head Neck Surg. 2002;127(4):315-323.

Theravent, Inc. website. http://www.proventtherapy.com/. Accessed June 18, 2020.

Vicini C, Dallan I, Canzi P, et al. Transoral robotic tongue base resection in obstructive sleep apnoea-hypopnoea syndrome: a preliminary report. ORL J Otorhinolaryngol Relat Spec. 2010;72(1):22-7.

Walker RP, Levine HL, Hopp ML, et al. Palatal implants: a new approach for the treatment of obstructive sleep apnea. Otolaryngol Head Neck Surg. 2006;135(4):549-554.

Walsh JK, Griffin KS, Forst EH, et al. A convenient expiratory positive airway pressure nasal device for the treatment of sleep apnea in patients non-adherent with continuous positive airway pressure. Sleep Med. 2011 Feb;12(2):147-52.

Woodson BT, Derowe A, Hawke M, et al. Pharyngeal suspension suture with repose bone screw for obstructive sleep apnea. Otolaryngol Head Neck Surg. 2000;122(3):395-401.

Woodson BT, Soose RJ, Gillespie MB, et al.; STAR Trial Investigators. Three-year outcomes of cranial nerve stimulation for obstructive sleep apnea: the STAR trial. Otolaryngol Head Neck Surg. 2016 Jan;154(1):181-8.

Woodson BT, Gillespie MB, Soose RJ, et al.; STAR Trial Investigators. Randomized controlled withdrawal study of upper airway stimulation on OSA: short- and long-term effect. Otolaryngol Head Neck Surg. 2014 Nov;151(5):880-7.

Woodson BT, Nelson L, Mickelson S, et al. A multi-institutional study of radiofrequency volumetric tissue reduction for OSAS. Otolaryngol Head Neck Surg. 2001;125(4):303-311.

Woodson BT, Steward DL, Mickelson S, et al. Multicenter study of a novel adjustable tongue-advancement device for obstructive sleep apnea. Otolaryngol Head Neck Surg. 2010 Oct;143(4):585-90.

Policy History/Revision Information

Date	Summary of Changes
07/01/2021	Coverage Rationale • Replaced references to “InterQual® 2020” with “InterQual® 2021” Supporting Information • Archived previous policy version CS116LA.W

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.
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