

OBSTRUCTIVE SLEEP APNEA TREATMENT

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, 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 MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

When deciding coverage for these services, the enrollee specific document must be referenced as some Certificates of Coverage (COC) and Summary Plan Descriptions (SPD) contain explicit

exclusions or limitations of coverage. Some, but not all, benefit documents allow for the use of patient selection criteria in determining coverage.

COVERAGE RATIONALE

Nonsurgical Treatment

Removable oral appliances are proven and medically necessary for treating obstructive sleep apnea (OSA) as documented by polysomnography. Refer to the Medical Policy titled [Polysomnography and Portable Monitoring for Sleep Related Breathing Disorders](#) for further information. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Oral Appliances (Mandibular Advancement Devices), A-0341 (ACG).

Removable oral appliances are unproven and not medically necessary for treating central sleep apnea.

This type of sleep apnea is caused by impaired neurological function, and these devices are designed to manage physical obstructions.

Nasal dilator devices are unproven and not medically necessary for treating obstructive sleep apnea (OSA).

There is insufficient clinical evidence supporting the safety and efficacy of nasal dilators for treating OSA. Results from available studies indicate that therapeutic response is variable among the participants. Further research from larger, well-designed studies is needed to evaluate the effectiveness of the device compared with established treatments for OSA, to determine its long-term effectiveness and to determine which patients would benefit from this therapy.

Surgical Treatment

The following surgical procedures are proven and medically necessary for treating obstructive sleep apnea as documented by polysomnography. Refer to the medical policy titled [Polysomnography and Portable Monitoring for Sleep Related Breathing Disorders](#) for further information.

- **Uvulopalatopharyngoplasty (UPPP)**
For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Uvulopalatopharyngoplasty (UPPP), A-0245 (ACG).
- **Maxillomandibular advancement surgery (MMA)**
For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Maxillomandibular Osteotomy and Advancement, A-0248 (ACG).
- **Multilevel procedures whether done in a single surgery or phased multiple surgeries.**
There are a variety of procedure combinations, including mandibular osteotomy and genioglossal advancement with hyoid myotomy (GAHM). For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Mandibular Osteotomy, A-0247 (ACG).

Radiofrequency ablation of the soft palate and/or tongue base is proven and medically necessary for treating mild to moderate obstructive sleep apnea as documented by polysomnography. Refer to the medical policy titled [Polysomnography and Portable Monitoring for Sleep Related Breathing Disorders](#) for further information. In addition to the criteria listed above, radiofrequency ablation of the soft palate and/or tongue base is medically necessary for patients who fail to improve with or cannot tolerate an adequate trial of continuous positive airway

pressure (CPAP) or another device, including bi-level positive airway pressure (BiPAP), auto-titrating positive airway pressure (APAP) and/or oral appliances.

According to the American Academy of Sleep Medicine (AASM) the diagnosis of OSA is confirmed if the number of obstructive events[†] (apneas, hypopneas + respiratory event related arousals) on polysomnography (PSG) is greater than 15 events/hour or greater than 5/hour in a patient who reports any of the following: unintentional sleep episodes during wakefulness; daytime sleepiness; unrefreshing sleep; fatigue; insomnia; waking up breath holding, gasping or choking; or the bed partner describing loud snoring, breathing interruptions or both during the patient's sleep (Epstein et al., 2009).

[†] The frequency of obstructive events is reported as an apnea + hypopnea index (AHI) or respiratory disturbance index (RDI). RDI has at times been used synonymously with AHI, but at other times has included the total of apneas, hypopneas and respiratory effort related arousals (RERAs) per hour of sleep. When a portable monitor is used that does not measure sleep, the RDI refers to the number of apneas plus hypopneas per hour of recording.

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

The following surgical procedures are unproven and not medically necessary for treating obstructive sleep apnea:

- Laser-assisted uvulopalatoplasty (LAUP)
- Palatal implants
- Lingual suspension - also referred to as tongue stabilization, tongue stitch or tongue fixation
- Transoral robotic surgery (TORS)

There is insufficient evidence to conclude that laser-assisted uvulopalatoplasty (LAUP) results in improved AHI or secondary outcomes. Some studies saw a worsening of symptoms as well as increased complications.

Results of studies provide preliminary but inconsistent evidence that palatal implants benefit patients with mild to moderate OSA. However, the magnitude of the benefits has been small; the largest randomized controlled trial (RCT) found that average OSA worsened in spite of treatment; and the available studies involved ≤ 1 year of patient monitoring after treatment. Additional studies are needed to determine the role of palatal implants in the management of OSA

There is insufficient evidence to support the safety, efficacy and long-term outcomes of lingual suspension in the treatment of OSA. The published peer-reviewed medical literature includes a few small, uncontrolled studies with short-term follow-up. Large, controlled studies, with long-term follow-up, comparing lingual suspension to established procedures are necessary.

There is insufficient evidence to support the safety, efficacy and long-term outcomes of transoral robotic surgery (TORS) in the treatment of OSA. Large, controlled studies, with long-term follow-up, comparing TORS to established procedures are necessary.

Follow-up polysomnography should be performed following surgery to evaluate response to treatment (Kushida et al., 2006; Ferguson et al., 2006). Refer to the medical policy titled [Polysomnography and Portable Monitoring for Sleep Related Breathing Disorders](#) for further information.

APPLICABLE CODES

The Current Procedural Terminology (CPT[®]) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT [®] Code	Description
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
21198	Osteotomy, mandible, segmental;
21199	Osteotomy, mandible, segmental; with genioglossus advancement
21206	Osteotomy, maxilla, segmental (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

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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
S2080	Laser-assisted uvulopalatoplasty (LAUP)
S8262	Mandibular orthopedic repositioning device, each

ICD-9 Diagnosis Code	Description
327.23	Obstructive sleep apnea (adult) (pediatric)

ICD-10 Codes (Preview Draft)

In preparation for the transition from ICD-9 to ICD-10 medical coding on **October 1, 2015**^{*}, a sample listing of the ICD-10 CM and/or ICD-10 PCS codes associated with this policy has been provided below for your reference. This list of codes may not be all inclusive and will be updated to reflect any applicable revisions to the ICD-10 code set and/or clinical guidelines outlined in this policy. **The effective date for ICD-10 code set implementation is subject to change.*

ICD-10 Diagnosis Code (Effective 10/01/15)	Description
G47.33	Obstructive sleep apnea (adult) (pediatric)

DESCRIPTION OF SERVICES

Obstructive sleep apnea (OSA) is a breathing disorder that is defined by either a 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 patients with OSA is characterized by 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.

OSA can occur at one or more "levels" of the nasopharyngo-tracheal airway. Type I disease involves narrowing or collapse of the retropalatal region. Type III disease involves collapse in the retrolingual area (tongue base). Type II disease involves narrowing or collapse of both the retropalatal and retrolingual areas. Major OSA is usually a multi-level disorder, with tissues of the soft palate, lateral pharyngeal walls and tongue base all contributing to airway impingement. Intra-nasal tissue, adenoids and tonsils may also play a role (AASM, 2008).

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 and surgery. Positive airway pressure therapy may use any one of the following techniques: continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP), bilevel positive airway pressure (BiPAP), variable positive airway pressure (VPAP).

Non-surgical oral appliances, worn during sleep, are intended to treat OSA 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.

Oral appliances are recommended for treating OSA in ANY of the following circumstances:

- Mild OSA AND patient is unable to tolerate positive airway pressure (PAP) therapy OR refuses PAP
- Moderate to severe OSA as a component of treatment that includes additional modalities such as PAP therapy with reduced pressure
- As a standalone treatment for moderate to severe OSA, if patient is unable to tolerate PAP therapy OR refuses PAP, although this may not be the most effective therapy.

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 (Epstein et al., 2009)

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 (Ventus Medical website).

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.

Nonsurgical**Oral Appliances**

An Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness report states that despite no evidence or weak evidence on clinical outcomes, given the large magnitude of effect on the important intermediate outcomes of apnea-hypopnea index (AHI), Epworth Sleepiness Scale (ESS) and other sleep study measures, overall, the strength of evidence is moderate that mandibular advancement devices (MAD) are an effective treatment for OSA in patients without comorbidities (including periodontal disease) or excessive sleepiness. However, the strength of evidence is insufficient to address which patients might benefit most from treatment. The strength of evidence is insufficient regarding comparisons of different oral devices. Despite no evidence or weak evidence on clinical outcomes, overall the strength of evidence is moderate that the use of CPAP is superior to MAD. However, the strength of evidence is insufficient to address which patients might benefit most from either treatment. Comparative studies focusing on long-term follow-up and clinical outcomes are needed (Balk et al., 2011).

In a randomized crossover trial, Phillips et al. (2013) compared the effects of continuous positive airway pressure (CPAP) and mandibular advancement device (MAD) therapy on cardiovascular and neurobehavioral outcomes in patients with obstructive sleep apnea (OSA). A total of 126 patients with moderate to severe OSA were randomly assigned to a treatment order, and 108 completed the trial with both devices. Health outcomes were similar after 1 month of treatment. CPAP was more efficacious than MAD in reducing AHI but compliance was higher with MAD. The 24-hour mean arterial pressure was not inferior on treatment with MAD compared with CPAP; however, overall, neither treatment improved blood pressure. Sleepiness, driving simulator performance and disease-specific quality of life improved on both treatments by similar amounts, although MAD was superior to CPAP for improving four general quality-of-life domains.

Holley et al. (2011) conducted a retrospective analysis evaluating the efficacy of an adjustable oral appliance (aOA) in comparison with continuous positive airway pressure (CPAP) for treating obstructive sleep apnea (OSA). A total of 497 patients were given an aOA. The aOA reduced the mean apnea-hypopnea index (AHI) to 8.4 ± 11.4 , and 70.3%, 47.6% and 41.4% of patients with mild, moderate and severe disease achieved an AHI < 5, respectively. Patients using an aOA decreased their mean Epworth Sleepiness Score by 2.71 at follow-up. CPAP improved the AHI by -3.43 when compared with an aOA, but when adjusted for severity of disease, this difference only reached significance for patients with severe disease (-5.88). However, 70.1% of all patients achieved an AHI < 5 using CPAP compared with 51.6% for the aOA. Baseline AHI was a significant predictor of achieving an AHI < 5, and age showed a trend toward significance. In comparison with past reports, more patients in this study achieved an AHI < 5 using an aOA. The authors concluded that aOAs are comparable to CPAP for patients with mild disease; however, CPAP is superior for patients with moderate to severe disease.

In a multicenter, randomized controlled trial (n=101), Lam et al. (2007) compared the effectiveness of three commonly used non-surgical treatment modalities in patients with mild to moderate OSA. Treatment groups consisted of conservative measures (sleep hygiene) only, continuous positive airways pressure (CPAP) in addition to conservative measures or an oral appliance in addition to conservative measures. The severity of sleep-disordered breathing was decreased in the CPAP and oral appliance groups compared with the conservative measures group, and the CPAP group was significantly better than the oral appliance group. Overall, CPAP produced the best improvement in terms of physiological, symptomatic and quality of life measures, while the oral appliance was slightly less effective.

A Cochrane review concluded that while CPAP appears to be more effective in improving sleep disordered breathing, there is increasing evidence suggesting that oral appliances (OA) improve subjective sleepiness and sleep disordered breathing compared with a control. Until there is more definitive evidence on the effectiveness of OA in relation to CPAP, with regard to symptoms and

long-term complications, it would appear to be appropriate to recommend OA therapy to patients with mild symptomatic OSA, and those patients who are unwilling or unable to tolerate CPAP therapy. OA should not be considered as first choice therapy for OSA where symptoms and sleep disruption are severe (Lim et al., 2006; updated 2008).

Ferguson et al. (2006) conducted an evidence-based systematic review regarding the use of oral appliances for treating OSA and concluded that overall, patients with mild to severe OSA have a 52% chance of being able to control their sleep apnea using an appliance. Success rates ranged between 14 and 61% among patients with severe OSA (AHI defined as greater than 30 in some studies and greater than 40 in others). Better success rates were seen in patients with lower AHI. OAs are on the whole less effective than CPAP but may be better accepted by patients than nasal CPAP in studies where subjects used both treatments. OAs are not recommended as a first line treatment in patients with severe OSA. However, these patients might consider an OA if they have failed CPAP or upper airway surgery, recognizing that the results of OA therapy in severe OSA are unpredictable. The literature now provides better evidence for the efficacy of OAs and indications for use.

Tegelberg et al. (2003) compared two different degrees of mandibular advancement with an intraoral appliance in 74 male patients with mild to moderate OSA. Thirty-eight patients received a dental appliance with 50% advancement and 36 patients received a dental appliance with 75% mandibular advancement. Somnography was performed pre-treatment and after one year of treatment. Fifty-five patients completed followup after one year of treatment. In the group of 50% advancement, normalization (an apnea index of <5 and apnea/hypopnea index <10) was observed in 79% of the group. In the group of 75% advancement, normalization was observed in 73% of the group. Less than 5% of the patients reported symptoms from the stomatognathic system; one-third of the patients reported headaches more than once a week. Headaches significantly decreased after one year of treatment.

Thirty-five patients diagnosed with OSA unable to tolerate or non-compliant with CPAP were studied by Prathibha et al. (2003). These patients underwent sleep studies, used intraoral appliances for three months and had a repeat sleep study performed while using the appliance. Thirty-one patients completed the study. Patients with a pre-study AHI <20 benefited from the appliance, while the authors concluded that those patients with a pre-study AHI >20 did not.

Walker-Engstrom et al. (2002) randomized 95 patients with confirmed OSA to treatment with a dental appliance or uvulopalatopharyngoplasty. Patients underwent sleep studies before treatment and 1 year and 4 years after treatment. Thirty-two patients in the dental appliance group and 40 patients in the UPPP group completed the 4-year follow up. Success was defined as a reduction in the apnea index of at least 50%. The dental appliance group had a success rate of 81%; the UPPP group had a success rate of 53%. An apnea index of <5 or an apnea/hypopnea index <10 was observed in 63% of the dental-appliance group and 33% of the UPPP group. The compliance rate of the dental appliance group was 62%. Seventy-five percent of the UPPP group were satisfied with their results and required no further complementary treatment.

Gotsopoulos et al. (2002) evaluated the effect of a mandibular advancement splint (MAS) on daytime sleepiness and a range of other symptoms in 73 patients (59 men, 14 women) with mild to severe OSA. OSA severity subgroups revealed a predominance of moderate and severe OSA, with 41 patients (56%) and 21 patients (29%) in each subgroup, respectively. Using a randomized crossover design, patients received 4 weeks of treatment with MAS and a control device (inactive oral appliance). At the end of each treatment period, patients were reassessed by questionnaire, polysomnography, and multiple sleep latency tests. Participants experienced significantly improved mean sleep latency on the multiple sleep latency test and Epworth sleepiness scale score with the MAS compared with the control device. The proportion of patients with normal subjective sleepiness was significantly higher with the MAS than with the control device (82 versus 62%), but this was not so for objective sleepiness (48 versus 34%). Other OSA

symptoms were controlled in significantly more patients with the MAS than with the control device.

In a randomized, controlled crossover study, Mehta et al. (2001) evaluated the efficacy of a mandibular advancement splint (MAS) in 28 patients with mild to severe OSA. Patients underwent three polysomnographs with either a control oral plate, which did not advance the mandible, or a MAS. Complete response (CR) was defined as a resolution of symptoms and a reduction in apnea/hypopnea index (AHI) to <5/hour, and partial response (PR) as a $\geq 50\%$ reduction in AHI, but remaining ≥ 5 /hour. Twenty-four patients (19 men, 5 women) completed the protocol. Treatment outcome was similar across all categories of OSA severity, with complete response being achieved in some subjects with moderate and severe OSA. Subjective improvements with the MAS were reported by the majority of patients (96%). There were significant improvements in AHI, oxygen saturation and arousal index with MAS, compared with the control. The control plate had no significant effect on AHI and oxygen saturation. CR (n = 9) or PR (n = 6) was achieved in 62.5% of patients. The MAS is an effective treatment in some patients with OSA, including those patients with moderate or severe OSA.

Nasal Dilators

Preliminary evidence suggests that use of the Provent nasal device significantly improves the apnea-hypopnea index (AHI) and some other OSA outcomes during short-term and mid-term use of the device in patients with mild, moderate and severe OSA, compared with baseline values. In addition, compared with a sham device, the improvements were more pronounced. Most of the studies evaluated short-term outcomes (~3 months). The therapeutic response to the Provent device varied among the patients, so it is unclear which factors are predictive of treatment response. There was some evidence that the use of the Provent device improved sleep quality and decreased daytime sleepiness among OSA patients, decreased the observed amount of snoring and had no effect on sleep architecture. The device was well tolerated and adherence to the device was high. Most adverse events were mild, such as nasal discomfort and dry mouth.

Despite these promising findings, the quality of the evidence was low. In several studies, patients served as their own controls. Sample sizes were small, and there were a fair number of dropouts. Additional limitations included the variable use of high- and standard-resistance devices, self-reported adherence data and a heterogeneous patient population. Overall, there is some evidence to suggest that the Provent nasal device is a safe and efficacious treatment for approximately half of the OSA patient population. However, independent randomized controlled trials are needed to evaluate the effectiveness of the device compared with established treatments for OSA, and to evaluate its long-term effectiveness. Additionally, a better understanding of the clinical profile of patients who most likely benefit from this therapy is required (Hayes, 2013).

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.

Berry et al. (2011) conducted a multicenter randomized controlled trial investigating the efficacy of 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, 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 EPAP. 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, 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.

Patel et al. (2011) studied a one way nasal device using expiratory positive airway pressure (EPAP) to identify appropriate patients for the therapy and provide pilot data as to its potential mechanisms of action. Twenty patients with OSA underwent three nocturnal polysomnograms (NPSG) including diagnostic, therapeutic (with a Provent® nasal valve device) and CPAP. Nineteen of the 20 patients tolerated the device. The authors reported that the nasal valve device produced improvement in sleep disordered breathing in 75% of patients with OSA of varying severity, with 50% of patients reaching a clinically significant reduction in RDI. Although the study was not able to establish predictors of success or a definitive mechanism of action, the authors feel it helps define a restricted list of candidates for further investigation. A potential for bias exists due to manufacturer sponsorship of the study.

Walsh et al. (2011) evaluated tolerability, short-term efficacy and adherence of an expiratory positive airway pressure (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 prespecified efficacy criteria and underwent PSG3 after 5 weeks of EPAP treatment. Compared to PSG1, mean AHI was significantly lower at both PSG2

and PSG3. For most patients AHI at PSG3 was similar to AHI at PSG2. Device use was reported an average of 92% of all sleep hours. The authors concluded that improvements in AHI and Epworth Sleepiness Scale (ESS) scores, combined with the high degree of treatment adherence observed, suggest that the EPAP device tested may become a useful therapeutic option for OSA. Limitations of the study include lack of randomization and control, small sample size and short term follow-up. A potential for bias exists due to manufacturer sponsorship of the study.

In a multicenter, prospective study, Rosenthal et al. (2009) evaluated the efficacy of 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. 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. A potential for bias exists due to manufacturer sponsorship of the study.

Professional Societies

American Academy of Sleep Medicine (AASM)

The AASM makes the following recommendations:

- Continuous positive airway pressure (CPAP) is the preferred first line therapy for OSA;
- Although not as efficacious as CPAP, oral appliances (OAs) are indicated for use in patients with mild to moderate OSA who prefer OAs to CPAP, do not respond to CPAP, are not appropriate candidates for CPAP, fail treatment attempts with CPAP or fail treatment with behavioral measures such as weight loss or sleep position change;
- Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Until there is higher quality evidence to suggest efficacy, CPAP is indicated whenever possible for patients with severe OSA before consideration of oral appliances;
- Follow-up polysomnography should be performed following oral appliance therapy to evaluate response to treatment (Kushida et al., 2006; Epstein et al., 2009).

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 based on an AHRQ systematic review (Balk, et al., 2011). 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)
- Mandibular advancement devices as an alternative therapy to continuous positive airway pressure treatment is recommended for patients diagnosed with OSA who prefer mandibular advancement devices or for those with adverse effects associated with continuous positive airway pressure treatment. (Grade: weak recommendation; low-quality evidence) (Qaseem et al., 2013).

American Sleep Apnea Association (ASAA)

Oral appliances used to treat sleep apnea are worn in the mouth during sleep. Most appliances work by positioning the lower jaw slightly forward of its usual rest position. This small change is, in many people, enough to keep the airway open during sleep. Oral appliances are most effective in the treatment of mild to moderate sleep apnea, although they do provide a treatment alternative for patients with severe OSA who cannot or will not tolerate positive airway pressure therapy. Sometimes for more complicated sleep apnea, an oral appliance and CPAP are used in combination. In the United States, oral devices to treat OSA cannot be sold over the counter. They must be prescribed and fitted by a dentist who has sleep medicine experience (ASAA, 2013).

Surgical

An Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review concluded that CPAP remains the most effective treatment for OSA. The studies for surgical interventions are limited, and current evidence is insufficient to determine their relative effectiveness when compared to each other, to sham or no treatment or to other OSA interventions (Balk et al., 2011).

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. Further research is needed to better clarify patient selection, as well as efficacy and safety of upper airway surgery in those with OSA.

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 reassert themselves, prompting patients to seek further treatment for sleep apnea

Uvulopalatopharyngoplasty (UPPP)

Using conventional surgical instruments, UPPP removes excess tissue from the soft palate and pharynx. The tonsils are also removed if present (ASAA, 2013).

One RCT evaluated UPPP versus lateral pharyngoplasty for OSA hypopnea syndrome (OSAHS). This study found that lateral pharyngoplasty provided statistically significant improvements in daytime sleepiness and apnea-hypopnea index compared with UPPP; however, it was small (n=27) and involved a mean of only 8 months of follow-up (Cahali, 2004).

Wilhelmsson et al. (1999) conducted the largest study (n=95), with follow-up data provided in three other articles (Walker-Engstrom 2000; 2002, Ringqvist 2003). This RCT, which evaluated UPPP versus nonsurgical treatment with a mandibular advancement device, provides limited evidence that the mandibular advancement device is more effective than UPPP. Patients randomized to the device had significant improvements in apnea index, apnea-hypopnea index, and blood oxygen saturation, relative to patients randomized to UPPP. However, 38% of patients in the device treatment group were lost to follow-up or withdrew from the study due to noncompliance before 4 years of follow-up were completed.

Another RCT of UPPP was conducted by Lojander et al. (1996), who performed two parallel RCTs in which patients were assigned to CPAP (n=44) or UPPP (n=32) by a team of medical experts and then randomized to treatment or no treatment. Although the results of this study suggest that UPPP and CPAP reduced symptoms of sleep apnea, the design of this study prevents direct comparison of results obtained with UPPP versus CPAP. Considering only the UPPP arm of the trial, this procedure was found to provide statistically significant improvements in daytime sleepiness and snoring but not in decreases in blood oxygen saturation levels during sleep.

In a nonrandomized comparative study, Walker et al. (1997) investigated the efficacy and safety of UPPP (n=41) compared with LAUPP (n=38). The response rate, defined as a > 50% reduction in the postoperative respiratory disturbance index, was 51% of UPPP-treated patients and 47% of LAUPP-treated patients. Patients in the UPPP group had higher respiratory disturbance indexes prior to surgery (52.1) compared with those who underwent LAUPP (30.3), which may have had an impact on outcome.

Maxillomandibular Advancement Surgery (MMA)/Multilevel Surgery (MLS)

MMA is a procedure in which the mandible and hyoid bone are surgically shifted forward to alter the position of the pharyngeal muscles and the base of the tongue. In MMA, both the upper (maxillary) and lower (mandible) jaws are cut and reconfigured. GAHM is a procedure in which the genial tubercle, which serves as the anterior attachment of the tongue, and the hyoid bone are advanced following a limited mandibular osteotomy. The hyoid is fixed to the anterior margin of the mandible or, in a more recent modification, fixed to the thyroid cartilage. A partial GAHM consists of the same procedure, but the hyoid is not suspended or advanced. Both procedures are intended to expand the airway and reduce OSA (ECRI, 2011a).

Most of the published literature addressing maxillomandibular advancement (MMA) surgery for treatment of obstructive sleep apnea (OSA) is of case series design. The variety of surgical

techniques used, combinations of treatment, and patient selection criteria presents some difficulty in comparison of results. Additionally, variation in what was termed as outcome success inhibits comparison of results.

In a meta-analysis and systematic review of the clinical efficacy and safety of MMA in treating OSA, Holty et al. (2010) found that the mean apnea-hypopnea index (AHI) decreased from 63.9/h to 9.5/h following surgery. The pooled surgical success and cure (AHI <5) rates were 86.0% and 43.2%, respectively. Younger age, lower preoperative weight, lower AHI and greater degree of maxillary advancement were predictive of increased surgical success. Most patients reported satisfaction after MMA with improvements in quality of life measures and most OSA symptoms. The authors concluded that MMA is a safe and highly effective treatment for OSA.

Lin et al. (2008) conducted a systematic review and meta-analysis on outcomes in patients with sleep apnea/hypopnea syndrome (OSAHS) treated with multilevel surgery of the upper airway. After applying specific inclusion criteria, 49 multilevel surgery articles (58 groups) were identified including 1,978 patients. The mean minimal follow-up time was 7.3 months. Success was defined as a reduction in the apnea/hypopnea index (AHI) of 50% or more and an AHI of less than 20. The success rate was 66.4%, and the overall complication rate was 14.6%. The authors noted that while multilevel surgery for OSAHS is associated with improved outcomes, this clinical advantage is supported largely by level 4 evidence (case series without an internal control group). Future research should focus on prospective and controlled studies.

In a prospective, nonrandomized comparative study, Dattilo and Drooger (2004) assigned 57 patients with OSA to MMA surgery (n=15) or palatal surgery combined with genioglossus advancement and hyoid suspension (n=42). Daytime sleepiness scores decreased 72% after MMA versus 43% after the palatal and other procedures. Parallel improvements were seen in respiratory disturbance index, which decreased 83% after MMA versus 59% after the other procedures. Although these results suggest that MMA surgery is more effective than palatal surgery with genioglossus advancement and hyoid suspension, the statistical significance of differences between the treatment groups at baseline and after treatment was not reported.

Vilaseca et al. (2002) treated 20 patients with UPPP plus mandibular osteotomy with GAHM and concluded that patients with mild and moderate OSA and multilevel obstruction in the upper airway may benefit from UPPP plus GAHM. Mean AHI was reduced from 60.5 to 44.6. CT90 (percentage of time with oxyhemoglobin saturation below 90%) decreased from 39.5% to 25.1%. The overall surgical success rate was 35% but increased to 57% in patients with moderate OSAS and to 100% in mild OSA. In the group of severe OSA, the success rate was only 9%.

Riley et al. presented the results of several studies evaluating maxillomandibular surgery to treat OSA. There may be some overlap in the study populations reported. One of the early studies, published in 1989, reported a case series of patients with snoring, excessive daytime sleepiness (EDS), and OSA documented by polysomnography (PSG). Fifty-five patients underwent inferior sagittal osteotomy (ISO) and uvulopalatopharyngoplasty (UPPP). "Responder" was defined as a respiratory distress index of < or = 20 and an RDI reduction of at least 50%, and a normal oxygen saturation. The mean preoperative RDI was 58.7, and postoperatively was 11.8; mean presurgical O₂ saturation was 71.5, and postsurgically 87.1. Postoperative PSG showed that 67% (n=37/ 55) of patients with ISO were responders, 80% had a reduction of more than 50% of apnea index (AI). Improvement in hypertension, and subjective improvement in snoring and memory was reported. For patients receiving maxillomandibular advancement surgery, mean presurgical RDI was 67.8, and postsurgically was 9.3; preoperative O₂ saturation was 65.9% and postoperatively, 87.2% (still below normal, but markedly improved.). All 25 patients reported subjective improvement in snoring and excessive daytime sleepiness.

Riley reported on another series of 40 patients who had failed anterior mandibular osteotomy (AMO) with or without uvulopalatopharyngoplasty, underwent MMA. Patients had fiberoptic pharyngoscopy, cephalometric radiographs and PSG prior to MMA and at 6 months

postoperatively. Success was defined as an RDI of < 20 with at least a 50% reduction in respiratory events and a normal O₂ saturation. Presurgical RDI was reported as 66.8 and postsurgical, 9.1. Surgical success was reported for 97% of patients; of the 18 patients who had used nasal continuous positive airway pressure (CPAP) preoperatively, all reported that MMA was equally effective. Despite a reported 20% mandibular relapse rate, OSA was reported as controlled in that group. The investigators concluded that MMS was as effective as CPAP in treating OSA (Riley, 1990a).

A second series of 30 patients was reported on in 1990b. This group of 30 consecutive patients with OSA had failed to comply with CPAP treatment and had hypopharyngeal-retrolingual obstruction with or without oropharyngeal-palatal obstruction. Twenty-five of the thirty patients underwent UPPP, and all 30 patients underwent MMA. Pretreatment RDI was 72.0, on-CPAP RDI was 8.6, and post-treatment RDI was 8.8. Marked improvement in O₂ saturation was reported postoperatively. At 6-month follow-up, all patients reported marked improvement in excessive daytime sleepiness and 93% reported that snoring was controlled. No statistical difference was found between treatment with CPAP and surgical treatment with MMA or MMA plus UPPP.

A 1993 study by Riley et al., reported on a large case series of 415 OSA patients (although only 306 patients completed the study). Patients received tiered therapy: patients with soft palate obstruction received UPPP; patients with retrolingual obstruction had MMA; patients with retrolingual and soft palate obstruction received genioglossal advancement with hyoid myotomy, and finally, patients who did not improve with UPPP or genioglossal advancement with hyoid myotomy, were offered MMA. Success was defined as PSG results equivalent to a two-night baseline CPAP or RDI < 20 with at least a 50% reduction in RDI, and O₂ saturation levels comparable to those while on CPAP. Mean presurgical RDI was 55.8, on CPAP was 7.4, and post-surgical was 9.2. Eighty-one percent of patients reported marked improvement in EDS, 78% reported snoring was controlled. The overall reported success rate was 76.5%. Sixty-one percent of patients having UPPP or genioglossal advancement with hyoid myotomy had successful results; 97% of patients undergoing MMA were reported as having successful results. The authors concluded that there was no significant difference in success between CPAP and surgery. They reported a 95% long-term success rate with the staged surgical process.

Most recently, in 2000, Riley reported on a case series of 40 patients treated between 1985 and 1995, to report long-term results of MMA with genioglossus and hyoid advancement. Success was reported as improvement in snoring, EDS, and PSG data comparable to that found with CPAP or postoperative RDI < 20 with a 50% reduction from presurgical level and O₂ saturation equivalent to that found with CPAP. Ninety percent (n=36/40) of patients were determined to have long-term success. A major shortcoming of this report, however, is that the method of patient selection for inclusion was not reported.

Neruntarat (2003a) studied the short term results of genioglossus advancement and hyoid myotomy with suspension in 31 patients with OSA. Six to 8 months post-surgery, the mean RDI decreased from 48.2 (+/- 10.8) to 14.5 (+/- 5.8). The lowest oxygen saturation increased from 81.8% (+/- 3.8) to 88.8% (+/- 2.9). Responders were defined as patients who had a reduction in RDI of at least 50% and an RDI of less than 20 after surgery. Using these criteria, 70% of the patients responded to the surgery.

Neruntarat (2003b) reported the long term results of genioglossus advancement and hyoid myotomy with suspension in 46 patients with OSA. The mean pre-operative RDI was 47.9 (+/- 8.4). The follow-up time ranged from 37 to 46 months. The mean RDI at follow-up was 18.6 (+/- 4.1).

Lee et al. (1999) published results of a prospective study of 48 patients with OSA. Patients with nasal obstruction underwent nasoseptoplasty or treatment with nasal corticosteroid; then had UPPP and anterior mandibular osteotomy (AMO) or inferior sagittal osteotomy (ISO). Patients

then were evaluated by PSG at 4-6 months, and those who were non-responders were given MMA (n=3). "Responder" was defined as an exhibitor of an RDI < 20 and with an O2 saturation > 95%. Thirteen patients did not complete the trial. Sixty-four percent (n=24/35) of patients were responders to UPPP and AMO or ISO. All three patients receiving MMA, responded to the treatment. The authors concluded that, in a properly selected patient population, staged reconstruction of the airway is efficacious.

A study by Prinsell et al. (1999), reviewed the cases of 50 patients with OSA by PSG (RDI > 15, O2 saturation < 90%, and EDS) and with oropharyngeal narrowing caused by macroglossia with retropositioned tongue base, who underwent MMA. Success was defined by the authors as: RDI < 15, O2 saturation > 80%, and apnea index (AI) < 5, OR a reduction in RDI and AI > 60% and an AI < 10. Findings were that all patients reported elimination of EDS, and that there was significant improvement in RDI, AI, O2 saturation, number of desaturations, blood pressure, BMI and sleep parameters. The authors concluded that surgery produced results comparable to use of CPAP.

Hochban et al. (1997) reported on 38 patients with an RDI of > 20 who underwent MMA with a goal of 10 mm of maxillary and mandibular advancement. Twenty-four of thirty-eight patients accepted a 3-month course of CPAP prior to surgery. All but one patient experienced a reduction in RDI to < 10 and subjective symptoms were resolved in all patients.

Conradt et al. (1997) reported on a small prospective study of 15 patients with EDS and RDI > 20. Patients were offered a three-month trial of CPAP prior to surgery, and then MMA with a goal of 10 mm maxillary and mandibular advancement. Preoperative RDI/AI were 51.4/33.6, on-CPAP 3.9/1.0, at 6-12 weeks postoperative, 5.0/2.3, and at 2 years postoperative 8.5/1.3.

There remains a moderate amount of disagreement over patient selection, with some proponents recommending advancement of 10 mm up to 15 mm to achieve functional effect. There is also some disagreement over the order of staging procedures, though the generally accepted order of intervention is to progress from least-invasive to most-invasive (Coleman, 1999).

Radiofrequency Ablation of the Soft Palate and/or Tongue

Radiofrequency tissue volume reduction (RFTVR) involves the use of low-intensity radiofrequency energy to shrink the size of the uvula, soft palate and/or tongue. Somnoplasty™ and Coblation® are two trade names using this technology. Multiple treatments are often necessary, and it may be performed in conjunction with other therapies (ECRI, 2011b).

A meta-analysis by Farrar et al. (2008) looked at sixteen studies using radiofrequency ablation (RFA) to treat OSA. The study found a 31% reduction in short-term Epworth Sleepiness Scale (ESS), which was maintained beyond 12 months. RFA resulted in a 31% reduction in short term and a 45% reduction in long-term respiratory disturbance index (RDI) levels. Short-term results of the lowest O2 saturations failed to demonstrate improvement. RFA seems to be a clinically effective tool that reduces ESS scores and RDI levels in patients with OSA syndrome. The procedure should be considered a valid treatment option for patients who refuse or are unable to tolerate continuous positive airway pressure.

Results of a randomized placebo-controlled trial comparing RFTVR and sham RFTVR of the tongue base, or tongue base and palate, with nasal CPAP suggested that CPAP provided somewhat better results, since AI and AHI scores were lower when CPAP was used. However, these benefits were obtained only if patients complied adequately with CPAP treatment. Data obtained with the FOSQ and the ESS suggested that CPAP and RFTVR provided comparable improvements in OSA (Woodson 2003). Although upper airway RFTVR and CPAP were also found to provide comparable benefits in a small retrospective case-matched comparative trial and a prospective nonrandomized comparative study, none of the studies evaluating RFTVR versus CPAP involved any follow-up after the post-treatment assessment (Woodson, 2001; Steward, 2004). Therefore, it is not known if RFTVR provided durable benefits.

Two reviewed studies compared RFTVR of the palate and uvula and LAUPP in a randomized design. Although results of one study suggested that these two procedures provided similar benefits, the statistical significance of differences between the RFTVR and LAUPP groups was not reported (Atef, 2005). In addition, the second study was small (n=17) and indicated that both RFTVR (palate) and LAUPP reduced snoring but did not significantly reduce other symptoms of mild sleep-disordered breathing (Terris, 2002a). In one randomized study, RFTVR of palate and uvula was compared to radiofrequency channeling (Bassiouny, 2007). Both methods were equally effective at 4 months post-treatment, the date of the final follow-up. Both methods significantly improved snoring and OAS. However, there was a nonsignificant trend that RFTVR may achieve improvements faster and may have a higher success and cure rates for OAS (50% and 45%, respectively) than the channeling method (40% and 25%, respectively). It is not known whether the treatment effect can be maintained beyond the 4 months follow-up.

Hofmann et al. (2006) compared temperature controlled RFTVR to conventional surgery using a non-randomized comparative 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.

Laser-Assisted Uvulopalatoplasty (LAUP)

Two of the reviewed studies were randomized trials that evaluated LAUPP. Ferguson et al. (2003) conducted a small RCT (n=45) with 8 months of follow-up to evaluate LAUPP versus no treatment for mild OSA. Although patients who underwent an average of 2.4 LAUPP 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. (2002a) also conducted a randomized trial of LAUPP but used a randomized crossover design in which patients were randomly assigned to LAUPP 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 LAUPP 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.

An RCT conducted by Larrosa et al. (2004) focused primarily on LAUPP for treatment of snoring; however, it included some patients with mild OSA and evaluated outcomes other than snoring intensity. Patients were randomized to LAUPP 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 LAUPP treatment group in snoring, daytime sleepiness, apnea-hypopnea index, or QOL measures. A shortcoming of the trial is that patients underwent only one LAUPP treatment rather than the multiple treatments provided by Terris and Ferguson.

In addition to these RCTs, one nonrandomized comparative study investigated the efficacy and safety of LAUPP (n=38) compared with UPPP (n=41) (Walker, 1997). The response rate, defined as a > 50% reduction in the postoperative respiratory disturbance index, was 47% of LAUPP-treated patients and 51% of UPPP-treated patients. Patients in the LAUPP group had lower respiratory disturbance indexes prior to surgery (30.3) compared with those who underwent UPPP (52.1), which may have affected treatment outcomes.

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 LAUPP 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.

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

Palatal Implants

Palatal implants consist of three small woven polyester 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® is a trade name 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 (Pillar website).

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 were 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 extremely 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) 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.

In a multi-institution, double-blind, placebo-controlled study, Steward et al. (2008) 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 outcomes measures with minimal morbidity, but overall effectiveness remains limited. The investigators concluded that further study is needed.

In a retrospective, nonrandomized, controlled study, 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. Most of the procedures other than palatal implantation were not defined clearly. After a mean follow-up of 8.1 months, mean AHI for the Palatal Group had decreased from 13.8 to 12.13; however, this difference was not statistically significant compared with baseline. Using the criteria of AHI < 20 and > 50% reduction of AHI as "cured," Friedman reported that 7 (24%) Palatal Group patients and 43 (34%) of all patients were "cured." A serious shortcoming of this conclusion is that many patients had an AHI < 20 at baseline, particularly in the Palatal Group, which had a baseline AHI of 13.8.

Walker et al. (2006) 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 25.14 at baseline to 22.15 at 90 days follow-up. Although this decrease was small, it was statistically significant (P=0.05). The AHI score was reduced to below 10 in 12 (23%) patients; however, 18 (34%) patients experienced an increase in their AHI score.

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; Nordgard, 2007).

Lingual Suspension/Tongue Fixation

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

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.

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.

Kuhnel et al. (2005) conducted a prospective nonrandomized study (n=28) to demonstrate the efficacy of tongue base suspension with the Repose System in the treatment of OSA. PSG was performed before as well as three and 12 months after surgery. Lateral cephalometric radiography and videoendoscopy of the pharynx were performed preoperatively and postoperatively to identify morphological changes in the posterior airway space. A suspension suture anchored intraorally at the mandible was passed submucosally in the body of the tongue, with suture tightness adjusted individually. The posterior airway space was widened by at least 2 mm in 60% of cases. Daytime sleepiness improved subjectively in 67% of patients, and the RDI improved postoperatively in 55% of patients. The correlation between posterior airway space widening and the improvements in daytime sleepiness and respiratory disturbance index was not significant. The authors concluded that surgical intervention in obstructive sleep apnea syndrome with the Repose System does not result in permanent anatomical change in the posterior airway space.

Miller et al. (2002) conducted a retrospective analysis of the Repose System for the treatment of OSA to describe preliminary experience using the system in conjunction with UPPP in the multilevel surgical approach. The authors evaluated 19 consecutive patients undergoing UPPP and the Repose System tongue base suspension for the management of OSA during a one-year period (1998 through 1999). Fifteen patients had complete preoperative and postoperative PSG data. A 46% reduction in RDI was demonstrated at a mean of 3.8 months after surgery. The apnea index demonstrated a 39% reduction. The authors concluded that the Repose System in conjunction with UPPP has been shown to produce significant reductions in the RDI and apnea index, as well as a significant increase in oxygen saturation. Despite the improvement in these objective parameters, the overall surgical cure rate was only 20% (three of 15 patients) in this retrospective series. Further research is warranted to define the role of the Repose System in the management of obstructive sleep apnea patients.

Woodson et al. (2000) conducted a prospective multicenter uncontrolled study to evaluate the feasibility and short-term subjective effectiveness of a new tongue suspension technique using the Repose System in 39 patients with snoring and OSA. Twenty-three patients completed 1 month and 19 completed 2 months of follow-up. In OSA patients, activity level, energy/fatigue, and sleepiness improved. Two-month outcomes were less (activity level, energy/fatigue, and sleepiness). Fewer changes were observed in snorers than in OSA patients. There were 6 complications (18%), including sialadenitis (4), gastrointestinal bleeding (1), and dehydration (1) after the procedure. Authors concluded that further evaluation is required to demonstrate effectiveness.

DeRowe et al. (2000) performed minimally invasive technique for tongue-base suspension with the Repose system in 16 patients with sleep-disordered breathing. Fourteen patients reported an improvement in daytime sleepiness, and their bed partners reported an improvement in snoring. The mean respiratory distress index before surgery was 35. Two months after surgery, the mean

respiratory distress index was 17, an improvement of 51.4%. These preliminary results show the initial efficacy and safety of this new surgical procedure.

Transoral Robotic Surgery (TORS)

Based on studies using transoral robotic surgery to treat head and neck cancers, researchers are investigating the use of this technology for patients with obstructive sleep apnea.

In a prospective, nonrandomized trial using historical controls, Lee et al. (2012) 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 and small sample size.

Friedman et al. (2012) 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 $60.5\% \pm 24.9\%$ for TORS versus $37.0\% \pm 51.6\%$ and $32.0\% \pm 43.3\%$ 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 design and small sample size.

Vicini et al. (2010) 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. Transoral robotic tongue base management in patients with OSAHS primarily related to tongue base hypertrophy is feasible and well tolerable. The authors found these preliminary results encouraging and worthy of further evaluation.

Professional Societies

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. It is most effective when there is an obvious anatomic deformity that can be corrected to alleviate the breathing problem. Otherwise, surgical options most often address the problem by reducing or removing tissue from the soft

palate, uvula, tonsils, adenoids or tongue. More complex surgery may be performed to adjust craniofacial bone structures. Surgical options may require multiple operations, and positive results may not be permanent (AASM, 2008).

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

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 challenge that confronts the surgeon is determining 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.

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, 2013).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Oral appliances for OSA are regulated by the FDA, but products are too numerous to list. See the following web site for more information (use product codes LRK or LQZ). Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. Accessed March 18, 2014.

The PROVENT® Professional Sleep Apnea Therapy (Ventus Medical, 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 March 18, 2014.

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

- The Somnoplasty™ System, manufactured by Olympus (formerly Gyrus ENT), received 510(k) approval (K982717) from the FDA on November 2, 1998. Intended for the reduction of the incidence of airway obstructions in patients suffering from upper airway resistance syndrome (URAS) or obstructive sleep apnea syndrome (OSAS), the system generates heat for creating finely controlled lesions at precise locations within the upper airway. As the tissue heals, it reduces tissue volume, opening the airway. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/K982717.pdf. Accessed March 18, 2014.
- 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 March 18, 2014.

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 March 18, 2014.

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 March 18, 2014.

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.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for oral appliances used for the treatment of obstructive sleep apnea (OSA). Local Coverage Determinations (LCDs) exist for oral maxillofacial prostheses used in the treatment of OSA. Refer to the LCDs for [Oral Maxillofacial Prosthesis](#), [Oral Appliances for Obstructive Sleep Apnea](#) and [Positive Airway Pressure \(PAP\) Devices for the Treatment of Obstructive Sleep Apnea](#).

Medicare does not have a National Coverage Determination (NCD) for surgical treatment of obstructive sleep apnea (OSA). Local Coverage Determinations (LCDs) exist for surgical treatment of OSA. Refer to the LCDs for [Surgical Treatment of Obstructive Sleep Apnea](#).

(Accessed March 6, 2014)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
08/01/2014	<ul style="list-style-type: none"> • Updated related policies reference link; <ul style="list-style-type: none"> ○ Replaced <i>Polysomnography and Portable Monitoring for Sleep Related Breathing Disorders</i> (title changed 08/01/14) with <i>Attended Polysomnography for Evaluation of Sleep Disorders</i>
06/01/2014	<ul style="list-style-type: none"> • Reorganized and renamed policy; combined content previously outlined in policies titled: <ul style="list-style-type: none"> ○ <i>Nonsurgical Treatment of Obstructive Sleep Apnea</i> ○ <i>Surgical Treatment of Obstructive Sleep Apnea</i> • Added benefit considerations language for <i>Essential Health Benefits for Individual and Small Group</i> plans to indicate: <ul style="list-style-type: none"> ○ For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)

	<ul style="list-style-type: none"> ○ Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans ○ The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage ● Updated coverage rationale: <ul style="list-style-type: none"> ○ Reformatted and relocated information pertaining to medical necessity review (when applicable); added language to indicate if service is "medically necessary" or "not medically necessary" to applicable proven/unproven statement ○ Removed references to specific device/product names ● Updated list of applicable ICD-10 codes (preview draft effective 10/01/15): <ul style="list-style-type: none"> ○ Changed tentative effective date of ICD-10 code set implementation from "10/01/14" to "10/01/15" ○ Added G47.33 ○ Removed G47.31 ● Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references ● Archived previous policy version 2013T0525H
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