

## ***Surgeries for Snoring, Obstructive Sleep Apnea Syndrome, and Upper Airway Resistance Syndrome***

**Effective:** September 1, 2021

**Next Review:** January 2022

**Last Review:** August 2021

### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

When conservative therapies for obstructive sleep apnea or upper airway resistance syndrome fail, established surgical interventions may be indicated.

### **MEDICAL POLICY CRITERIA**

**Note:** Contract language takes precedent over medical policy. Some member contracts have specific benefit limitations for orthognathic and telegnathic surgery.

#### **Pediatric Patients**

- I. Surgical treatment may be considered **medically necessary** for obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS) in pediatric patients (age 17 years and younger) when the request is not for any of the investigational procedures listed in Criteria III. below.
- II. Surgical treatment of snoring in the absence of documented obstructive sleep apnea in pediatric patients is considered **not medically necessary**.

- III. Surgical treatment of obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS) in pediatric patients is considered **investigational** including, but not limited to the following:
- A. Laser-assisted uvulopalatoplasty (LAUP) or volumetric tissue reduction
  - B. Palatal stiffening procedures, including but not limited to the following: Cautery-assisted palatal stiffening operation (CAPSO), injection of sclerosing agent (also known as snoreplasty), and implantation of palatal implants (also known as the pillar procedure)
  - C. Radiofrequency volumetric tissue reduction of the tongue base or palatal tissues
  - D. Tongue base suspension procedures, including but not limited to the AIRvance™ and the Encore™ tongue suspension systems
  - E. Uvulectomy

#### **Adult Patients**

- IV. Surgical procedures for the treatment of obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS) in adult patients (age 18 years and older) may be considered **medically necessary** when all of the criteria below (A- E.) are met:
- A. There is documentation of a sleep study performed within the last 3 years; and
  - B. One or more of the following procedures are requested:
    - a. Hyoid myotomy and suspension
    - b. Mandible osteotomy with or without genioglossus advancement
    - c. Maxillo-mandibular advancement (MMA)
    - d. Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty [UPPP], uvulopharyngoplasty)
    - e. Partial Glossectomy
  - C. Evidence, documented in the medical records, of exam findings that demonstrate upper airway collapse or obstruction as a reasonable cause of obstructive sleep apnea (e.g., palatine tonsils, epiglottis collapse, arytenoid collapse, lateral pharyngeal, craniofacial deficits).
  - D. The patient meets criteria for clinically significant obstructive sleep apnea (OSA) or upper airway resistance syndrome (UARS) as defined by Criteria 1. or 2. below:
    - 1. Clinically significant obstructive sleep apnea (OSA) defined as Criteria a. or b. below:
      - a. An AHI equal to or greater than 15 per hour; or
      - b. An AHI equal to or greater than 5 per hour with at least one of the following associated symptoms:
        - i. Excessive daytime sleepiness that is not better explained by other factors
        - ii. Documented unexplained hypertension

- iii. Ischemic heart disease or congestive heart failure
  - iv. Atrial fibrillation
  - v. History of stroke
  - vi. Obesity
  - vii. Diabetes and glucose intolerance
  - viii. Two or more of the following that are not better explained by other factors:
    - a.) Choking or gasping during sleep
    - b.) Recurrent awakenings during sleep
    - c.) Unrefreshing sleep with daytime fatigue
    - d.) Impaired concentration or cognition
    - e.) Insomnia
  - 2. Upper airway resistance syndrome (UARS) that is clinically significant is defined as greater than 10 alpha EEG arousals per hour.
- E. All of the following conservative medical therapies have failed to improve apnea/hypopnea including associated conditions such as excess daytime sleepiness:
- 1. Adjustment in sleep position when the sleep study shows improvement of sleep apnea when non-supine; and
  - 2. An adequate trial (at least 3 consecutive months [90 days] of continuous [at least 5 nights per week]) of a custom-made mandibular repositioning appliance has failed OR the patient is not an appropriate mandibular repositioning appliance candidate (see Policy Guidelines); and
  - 3. An adequate positive airway pressure (PAP, continuous or bi-level) trial that includes documentation of one or more of the following:
    - a. A minimum of 4 hours per night for 3 weeks of PAP usage; or
    - b. For patients who are PAP intolerant (unable to use PAP therapy for at least 4 hours per night for 5 nights or more per week), reasonable attempts to address any medical, mechanical, or psychological problems associated with PAP have been made (e.g., adjustment of pressure settings, appropriate medication and humidification, refitting of the mask, trial of alternative pressure delivery systems such as auto-adjusting positive airway pressure or bi-level positive airway pressure); or
    - c. For patients with severe psychological aversion to PAP, reasonable attempts have been made to complete a conventional desensitization program. Conventional desensitization programs include progressive steps intended to help the patient adapt first to the mask or nasal pillows, then to the air pressure. There may be more than one group or individual session, and the patient may work through the steps at home. Note: For patients with severe psychological aversion to PAP, monitoring during desensitization programs (e.g., PAP-NAP) is not necessary; or

- d. The patient is experiencing PAP failure, defined as AHI greater than 20 events per hour while using PAP after meeting Criterion E.3.a. or E.3.b. or E.3.c above.
- V. Surgical treatment is considered **not medically necessary** to treat obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS) in adult patients when Criteria IV. are not met, including PAP therapy refusal; or to treat snoring in the absence of documented obstructive sleep apnea in adult patients.
- VI. Surgical treatments of obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS) in adult patients not listed in Criterion IV.B. are considered **investigational** including, but not limited to the following:
  - A. Laser-assisted uvulopalatoplasty (LAUP) or volumetric tissue reduction
  - B. Palatal stiffening procedures, including but not limited to cautery-assisted palatal stiffening operation (CAPSO), injection of sclerosing agent (also known as snoreplasty), or implantation of palatal implants (also known as the pillar procedure)
  - C. Radiofrequency volumetric tissue reduction of the tongue base or palatal tissues
  - D. Tongue base suspension procedures, including but not limited to the AIRvance™ and the Encore™ tongue suspension systems
  - E. Uvullectomy

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## POLICY GUIDELINES

Not all patients are candidates for a mandibular repositioning device. Patients with tonsil hypertrophy criteria grade 3 or 4 on the Friedman scale, severe psychiatric diseases or dementia, untreated caries or periodontal disease, few teeth for anchoring a device, temporomandibular joint disorder, inadequate mandibular protrusive capacity, and class III malocclusion are examples of conditions that are contraindications to mandibular repositioning appliances.

## LIST OF INFORMATION NEEDED FOR REVIEW

### REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Current Symptomology
- Conservative Medical Therapies failed
- PAP Trial results
- Sleep Study results
- Documentation of an adequate trial of a mandibular repositioning device or documentation that the patient is not an appropriate appliance candidate with clinical rationale

- Evidence of airway obstruction or narrowing consistent with the procedure requested

## CROSS REFERENCES

1. [Prefabricated Oral Appliances for Obstructive Sleep Apnea](#), Allied Health, Policy No. 36
2. [Orthognathic Surgery](#), Surgery, Policy No. 137
3. [Absorbable Nasal Implant for Treatment of Nasal Valve Collapse](#), Surgery, Policy No. 209
4. [Phrenic Nerve Stimulation for Central Sleep Apnea](#), Surgery, Policy No. 212
5. [Hypoglossal Nerve Stimulation](#), Surgery, Policy No. 215

## BACKGROUND

### OBSTRUCTIVE SLEEP APNEA (OSA)

Obstructive sleep apnea (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. The hallmark symptom of OSA is excessive daytime sleepiness, and the typical clinical sign of OSA is snoring, which can abruptly cease and be followed by gasping associated with a brief arousal from sleep. The snoring resumes when the patient falls back to sleep, and the cycle of snoring/apnea/arousal may be repeated as frequently as every minute throughout the night.

Sleep fragmentation associated with the repeated arousal during sleep can impair daytime activity. For example, adults with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles (i.e., cars, trucks, heavy equipment). OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This, in turn, can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

A polysomnogram performed in a sleep laboratory and, in adults, home sleep apnea testing with a technically adequate device (see Appendix 1), are considered the gold standard tests used to diagnose OSA in adults.<sup>[1]</sup> Objective measures of OSA are compiled using polysomnography monitors, which document the number of apneic and hypopneic events per hour and combine them into the apnea-hypopnea index (AHI). The respiratory disturbance index (RDI) may be defined as the number of apneas, hypopneas and respiratory effort-related arousals (RERAs) per hour of sleep. The final diagnosis of OSA rests on a combination of objective and subjective criteria (e.g. AHI or RDI and excessive daytime sleepiness) that seek to identify those levels of obstruction which are clinically significant. When sleep onset and offset are unknown (e.g., in home sleep studies) the AHI or RDI may be calculated based on the number of apneas, hypopneas, and/or RERAs per hour of recording time.

An increase in mortality is associated with an AHI greater than 15. More difficult to evaluate is the clinical significance of patients with mild sleep apnea. Mortality has not been shown to be increased in these patients, and frequently the most significant manifestations reported by the patient are snoring, excessive daytime sleepiness, witnessed breathing interruptions, awakenings due to gasping or choking, nocturia, morning headaches, memory loss, irritability, or hypertension.<sup>[2, 3]</sup> The hallmark clinical symptom of OSA is excessive snoring, although it is important to note that snoring can occur in the absence of OSA. Isolated snoring in the

absence of medical complications, while troubling to the patient's bed partner, is not considered a medical problem requiring surgical intervention.

**Table 1. Definitions of Terms for Obstructive Sleep Apnea**

Terms	Definition
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by $\geq 90\%$ of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as $\geq 2$ missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with at least 3% oxygen desaturation or an arousal or either at least 4% arterial oxygen desaturation or an arousal (depending on the scoring criteria). Hypopneas in children are scored by a $\geq 50\%$ drop in nasal pressure and either a $\geq 3\%$ decrease in oxygen saturation or an associated arousal.
Apnea/Hypopnea Index (AHI)	The average number of apneas or hypopneas per hour of sleep
Obstructive sleep apnea (OSA)	Repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
Mild OSA	In adults: AHI of 5 to $<15$ In children: AHI $\geq 1$ to $<5$
Moderate OSA	In adults: AHI of 15 to $<30$ In children: AHI $\geq 5$ to $<10$
Severe OSA	Adults: AHI $\geq 30$ Children: AHI $\geq 10$
Continuous positive airway pressure (CPAP)	Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or Bi-level (Bi-PAP). CPAP is a more familiar abbreviation and will refer to all types of PAP devices.
PAP Failure	Usually defined as an AHI greater than 20 events per hour while using PAP (continuous or bi-level)
PAP Intolerance	PAP use for less than 4 h per night for 5 nights or more per week, or refusal to use PAP (continuous or bi-level). PAP intolerance may be observed in patients with mild, moderate, or severe OSA

## UPPER AIRWAY RESISTANCE SYNDROME (UARS)

Upper airway resistance syndrome (UARS) was initially used to describe a variant of OSA which is characterized by a partial collapse of the airway resulting in increased resistance to airflow. This resistance does not result in apnea, but the increased respiratory effort required to move air into the lungs results in fragmented sleep. These sleep fragmentations (RERAs) can be measured using an electroencephalogram (EEG). Diagnosis of UARS rests on documentation of more than 10 EEG arousals per hour of sleep along with documented episodes of abnormally negative intrathoracic pressure (i.e., more negative than -10 cm) associated with the EEG arousals. The drop in intrathoracic pressure can be measured by a variety of tests including use of an esophageal manometer, if available, as part of a polysomnogram. RERAs can also be detected absent manometry during polysomnography. It has been proposed that UARS is a distinct syndrome from OSA that may be considered a disease of arousal.

See Appendix 1 for additional information on diagnostic tests for OSA and UARS.

## **SURGICAL TREATMENTS FOR OSA AND UARS**

Medical therapy is considered the first-line treatment for OSA and UARS. These therapies include weight loss, various continuous positive airway pressure (CPAP) devices, or orthodontic repositioning devices in appropriate patients. See Appendix 2 for a description of medical devices used in the treatment of OSA and UARS. Most guidelines consider surgical intervention only after all appropriate medical treatments for OSA or UARS have failed. Conventional surgeries for OSA include uvulopalatopharyngoplasty (UPPP) and a variety of maxillofacial surgeries such as maxillo-mandibular advancement (MMA).

### **Uvulopalatopharyngoplasty (UPPP)**

UPPP involves surgical modification of the oropharynx and/or velopharynx by resection or reconstruction of the associated structures (soft palate, uvula, and associated muscles).<sup>[4, 5]</sup> The UPPP procedure enlarges the oropharynx but cannot correct obstructions in the hypopharynx. Therefore, if hypopharynx obstruction is identified, then alternate procedures are considered. In addition, patients who fail UPPP may be candidates for additional procedures, depending on the site of obstruction. Additional or alternate procedures include hyoid suspensions, maxillary and mandibular osteotomies, and mandibular and maxillary advancement surgery.

### **Mandibular and maxillary advancement (MMA) surgery**

Mandibular and maxillary advancement (MMA) surgery (may also be referred to as telegnathic surgery) is more extensive and is proposed for patients who do not have an adequate response to UPPP or other procedures, or who have mandibular or maxillary deficiency. These surgeries may be used to correct obstruction of the hypopharynx, oropharynx, or velopharynx; the areas of the full length of the throat.

### **Laser assisted uvuloplasty (LAUP)**

LAUP is an outpatient procedure that has been proposed as a treatment of snoring with or without associated OSA. In this procedure, the tissues of the soft palate (palatal tissues) are reshaped using a laser. The extent of the surgery is typically different than standard UPPP, since only part of the uvula and associated soft-palate tissues are reshaped. The procedure, as initially described, does not remove or alter tonsils or lateral pharyngeal wall tissues. The patient undergoes from 3 to 7 sessions at 3- to 4-week intervals. LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, raising unique issues of safety and effectiveness.

### **Palatal stiffening procedures and radiofrequency tissue reduction**

#### **Radiofrequency ablation of the soft palate and radiofrequency volumetric reduction of the tongue base (RFTBR)**

Radiofrequency energy is used to produce thermal lesions within the tissues. Radiofrequency devices transmit low frequency energy that causes ionic friction, which leads to coagulation necrosis, inflammation, and fibrosis.<sup>[6]</sup> These procedures may reduce the volume of soft tissue and may stiffen the tissue due to the creation of a submucosal scar. Radiofrequency based treatments to modify tissues of the soft palate have historically been referred to as somnoplasty.

### Cautery assisted palatal stiffening procedure (CAPSO)

This palatal stiffening procedure uses cautery (electrically heated probes) to induce a midline palatal scar designed to stiffen the soft palate to eliminate excessive snoring.

### Other palatal stiffening procedures

Other palatal stiffening procedures in use include injection sclerotherapy (also known as injection snoreplasty) and the pillar procedure, which involves the permanent implantation of braided polyester filaments into the soft palate through a needle.

### **Suspension of the tongue base and hyoid bone**

Tongue or hyoid bone suspension is performed through a small incision under the chin. A titanium screw is inserted under the chin in the posterior aspect of the lower jaw at the floor of the mouth. For tongue suspension, a loop of suture is passed through the tongue base and attached to the mandibular bone screw. For hyoid suspension a suspension loop is placed around the hyoid bone and anchored to the mandibular screw or to the thyroid cartilage. Once the suspension loop is attached to the screw it is pulled forward to advance the tongue base out of the airway, making it less likely for the base of the tongue to drop backward during sleep.

### **Uvulectomy**

This procedure surgically removes the uvula, the small tissue hanging from the soft palate at the back of the throat above the tongue. The uvula, which helps stiffen and shape the back of the throat and prevents food from going down the airway, is believed to be associated with excessive snoring.

### **Partial Glossectomy**

This procedure, also referred to as midline glossectomy, surgically removes a portion of the tongue in an effort to reduce tongue volume and open the oropharynx and/or hypopharynx.

### **REGULATORY STATUS**

The Somnoplasty® device has been cleared for marketing by FDA for RFA of palatal tissues for simple snoring and for the base of the tongue for OSA. FDA product code: GEI.

AIRvance® (Medtronic; formerly the Repose™ Bone Screw System from Influence) was cleared for marketing through the FDA 510(k) process in 1999 with intended use for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with prethreaded suture. It is indicated for the treatment of OSA and/or snoring.

The Encore™ Tongue Suspension System (Siesta Medical) received clearance for marketing by FDA in 2011, citing the PRELUDE III Tongue Suspension System (Siesta Medical) as a predicate device.

The Pillar® Palatal Implant System (originally Restore Medical, St. Paul, MN, acquired by Medtronic, Minneapolis, MN) is an implantable device that has been cleared for marketing through the FDA 510(k) process. The labeled indication of the device is as follows: “The Pillar™ Palatal Implant System is intended for the reduction of the incidence of airway



obstructions in patients suffering from mild to moderate OSA (obstructive sleep apnea).” FDA product code: LRK.

## EVIDENCE SUMMARY

Positive airway pressure (PAP, continuous or bi-level) is the most widely accepted medical therapy for treatment of obstructive sleep apnea (OSA) in adults and improvement of primary health outcomes such as cardiovascular disease, type 2 diabetes, and overall mortality associated with OSA.<sup>[5]</sup> Surgical interventions are being proposed as a second line treatment for patients who have experienced PAP failure or intolerance.

Appropriately controlled and adequately powered, long-term randomized controlled trials (RCTs) are needed to determine the safety and effectiveness of various surgical interventions for treatment of OSA.

The evidence suggests conventional uvulopalatopharyngoplasty (UPPP), hyoid suspension, mandible osteotomy, partial glossectomy, and maxillofacial surgeries such as maxillo-mandibular advancement (MMA), may improve health outcomes for some patients with OSA who have failed medical therapies for OSA.

- The available evidence does not currently support the widespread use of surgical interventions in the management of unselected patients with obstructive sleep apnea. Given the proven safety and efficacy of CPAP in patients with moderate and severe symptoms and significant sleep disordered breathing, surgery cannot be recommended as a first line therapy, ahead of positive airways pressure systems.<sup>[5, 7]</sup>
- While studies on UPPP and hyoid suspension procedures were not randomized, data from ten studies which included more than 750 patients consistently reported improved outcomes for patients with OSA as measured by postoperative polysomnographic assessment of sleep disturbance and compared with concurrent groups being treated with CPAP.<sup>[8]</sup>
- UPPP, hyoid suspension, mandible osteotomy, partial glossectomy and MMA procedures are widely practiced among surgeons in the United States. These procedures have been considered a standard of care in the medical community.<sup>[8]</sup>

Evidence is uncertain for use of other surgical interventions in the treatment of OSA, including but not limited to uvulectomy and minimally invasive surgical procedures such as laser-assisted uvuloplasty (LAUP), radiofrequency tongue base reduction (RFTBR), pillar stiffening procedures, and pillar implants. Therefore, the following evidence review will be focused on the investigational indications in this policy.

## SURGICAL TREATMENTS FOR OSA

### Technology Assessments and Systematic Reviews

A 2011 Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review entitled “Diagnosis and Treatment of Obstructive Sleep Apnea in Adults” included studies conducted only in adults, defined as over 16 years of age. The authors state the following regarding the available evidence for surgical interventions for the treatment of OSA:

<sup>[5]</sup>

- *The strength of evidence is insufficient to evaluate the relative efficacy of surgical interventions for the treatment of OSA.*
- *The strength of evidence is insufficient to determine the relative merits of surgical treatments versus CPAP.*
- *Due to the heterogeneity of interventions and outcomes examined, the variability of findings across studies, and the inherent bias of all but one study regarding which patients received surgery, it is not possible at this time to draw useful conclusions comparing surgical interventions with CPAP in the treatment of patients with OSA.*

The review cited the lack of head-to-head comparisons between CPAP and proposed surgical modalities, and the lack of study of any long-term health outcomes associated with OSA treatment.

Earlier evidence-based systematic reviews on the use of surgical therapies in OSA cited the lack of well-designed randomized controlled trials (RCTs) assessing different surgical techniques with inactive and active control treatments.<sup>[7, 9]</sup> These reviews were not able to make the highest-level recommendation supporting the use of any one surgical intervention. Limitations of studies include heterogeneous patient populations with mixed OSA severity, as measured by AHI; and lack of long-term followup. These reviews state that long-term follow-up of patients who undergo surgical correction of upper airway obstruction would help to determine whether surgery is curative, or whether the signs and symptoms of sleep apnea return, prompting patients to seek further treatment.

The 2009 systematic review by Franklin evaluated benefits and adverse effects of surgery for snoring and OSA.<sup>[10]</sup> The authors found only a small number of randomized controlled trials (RCTs) that assessed surgical procedures for snoring or sleep apnea. Key findings are as follows:

- Results from 45 studies reporting adverse events revealed persistent side effects after uvulopalatoplasty (UPP) and uvulopalatopharyngoplasty (UPPP) in about half the patients. Difficulty swallowing, globus sensation, and voice changes were especially common. The authors concluded that additional research with RCTs of surgery other than UPP and UPPP is needed, as these surgical procedures are related to a high risk of adverse effects, especially difficulty swallowing.
- Four RCTs, rated as high quality, were identified for laser-assisted palatoplasty (LAUP) and radiofrequency ablation (RFA).<sup>[11-14]</sup> Study results were mixed and inconclusive for Apnea/Hypopnea Index (AHI), and showed no benefit on daytime sleepiness or quality of life. Interpretation of this result is limited by the inclusion of studies with one-stage procedures and subjects whose main symptom was disruptive snoring.<sup>[13]</sup> The relevant trials are described in greater detail next.

## **RADIOFREQUENCY VOLUMETRIC TISSUE REDUCTION OF THE TONGUE BASE OR PALATAL TISSUES**

### **Systematic Reviews**

Baba (2015) performed a systematic review and meta-analysis that addressed the efficacy of temperature controlled radiofrequency tissue ablation (TCRFTA) to alleviate symptoms of OSA.<sup>[15]</sup> The analyses included three small nonrandomized comparative trials comparing TCRFTA with three different nonsurgical or surgical interventions and seven prospective case series (of which all but one were small). TCRFTA was categorized based on location: base of

tongue, soft palate and multilevel. Analysis showed significant reductions in respiratory disturbance index (RDI), Epworth Sleep Scale (ESS), lowest oxygen saturation (LSAT), and snoring for procedures performed at the base of the tongue. TCRFTA at the soft palate showed limited efficacy, although there was a paucity of studies in this area. Multilevel TCFFTA did show a significant reduction in RDI, in the short term. Analysis of AHI was not completed as this outcome was not consistently reported within the studies. The authors reported that the studies were generally of low quality and there was significant heterogeneity which did not allow for strong conclusions. Studies with longer-term outcomes would be useful in evaluating the benefits of this procedure.

In 2008, Farrar published a meta-analysis of RFA for the treatment of OSA in patients with a RDI of 5 or more.<sup>[6]</sup> Sixteen studies met the inclusion criteria; three were randomized and 13 were nonrandomized. Six studies treated both the base of the tongue and the soft palate, two treated the soft palate only, and eight ablated the base of the tongue only. The population was in the overweight, but not obese, category, with a mean BMI of 28.5. In half of the studies, the average baseline RDI was less than 30, and in six of the studies, the average baseline ESS was less than 10. The meta-analysis indicated a 31% reduction in both ESS and RDI. The lowest oxygen saturation level was not improved by RFA. The mean number of treatments required for patient satisfaction was 3.7 for the soft palate, 4.3 for the base of the tongue, and 4.8 for both sites (range, 3-7). Complications were noted in 4% of patients; two tongue abscesses progressed to airway obstruction requiring tracheotomy. Only two of the studies provided 2-year follow-up, with a 32% reduction in ESS and a 45% reduction in RDI. The number of patients who were successfully treated (e.g., 50% reduction in RDI) was not reported. This meta-analysis is limited by the inclusion of poor-quality uncontrolled studies.

### **Randomized Controlled Trials**

McKay (2020) published the results of a randomized controlled trial (RCT, multicenter, parallel-group, open-label) that compared multilevel surgery (modified uvulopalatopharyngoplasty and radiofrequency tongue volume reduction; n=51) and ongoing medical management (e.g., advice on sleep positioning, weight loss; n=51) for the treatment of OSA.<sup>[16]</sup> There was a statistically significantly greater improvement from baseline to six months in AHI in the surgery group (47.9 vs. 20.8) than in the ongoing medical management group (45.3 vs. 34.5, mean baseline-adjusted between-group difference, -17.6 events/h of sleep [95%CI, -26.8 to -8.4]; p<0.001) and in the ESS in the surgery group (12.4 vs 5.3) compared with the ongoing medical management group (11.1 vs 10.5, mean baseline adjusted between-group difference, -6.7 [95%CI, -8.2 to -5.2]; p<0.001). There were six serious adverse events in four participants in the surgery group and no serious adverse events in the ongoing medical management group. Although the results of this study did surpass the minimal clinically important difference for AHI, they did not meet the sufficiently important difference for AHI (the amount needed to account for the cost and potential morbidity of surgery), indicating that further studies are needed to establish the long-term effectiveness, safety, and cost-effectiveness of this surgical treatment for OSA. In addition, women were underrepresented in the trial and the study cohort was limited to a select population that excluded patients with severe obesity (BMI of 38 or greater), patients older than 70 years, and patients with retrognathia and significant comorbidities, limiting generalizability of the outcomes. No comparison of UPPP alone to RF tongue reduction alone or of these procedures alone compared to medical management was provided. Ultimately, the authors conclude “further research is needed to confirm these findings in additional populations and to understand clinical utility, long-term efficacy, and safety of multilevel upper airway surgery for treatment of patients with OSA.”

A single-blinded RCT of single-stage radiofrequency surgery of the soft palate was reported in 2009 by Back.<sup>[17]</sup> Thirty-two patients with mild OSA (AHI between 5 and 15), habitual snoring, and excessive daytime sleepiness according to subjective patient history, were randomized to a single session of RFA or sham ablation. There was no difference between the groups for baseline to posttreatment (4-6 months) changes in the Epworth Sleepiness Scale (ESS) (3-point improvement in ESS for both groups), reports of snoring (1-point improvement in both groups), AHI (no clinically significant change), or any other outcome measure. None of the patients reported any treatment-related symptoms or complications four months after treatment. Results of this small single-blinded RCT indicate that single-stage RFA of the soft palate is not effective for the treatment of mild OSA.

A RCT from 2009 by Fernandez-Julian compared efficacy and adverse effects of two tongue-based procedures (RFA or tongue-base suspension) when combined with UPPP in 57 patients with moderate-to-severe sleep apnea (AHI  $\geq 15$ ).<sup>[18]</sup> Patients with a BMI of 35 kg/m<sup>2</sup> or greater were excluded. Although interpretation of results is limited by the lack of a control group treated with UPPP alone, the success rate for combined RFA + UPPP (defined as a  $\geq 50\%$  reduction and final AHI  $< 15$ ) was 51%. BMI was the main predictor of success, with success rates of only 12.5% in patients with a BMI between 30 and less than 35 kg/m<sup>2</sup>.

A 2003 two-site RCT study by Woodson compared the use of multilevel RFA with the current criterion standard of CPAP.<sup>[12]</sup> The study included patients with mild obesity levels (BMI  $\geq 34$  kg/m<sup>2</sup>) who had mild to moderate sleep apnea with an AHI between 10 and 30. Statistically significant improvement was noted with RFA and CPAP over placebo in OSA-specific quality of life using the Functional Outcomes of Sleep Questionnaire. However, the small size of the trial resulted in most outcomes not being statistically significant. The same group of authors reported a further subgroup analysis from the same trial, focusing on the 26 patients randomized to the RFA arm of the trial to determine whether additional treatments improved outcomes.<sup>[19]</sup> Specifically, the authors focused on multilevel treatments on various combinations of palatal and tongue tissues. Greater improvements in quality of life were reported for those patients who had a total of five treatments compared with 3. Another subgroup analysis focused on multilevel treatments in 26 patients.<sup>[20]</sup> This subgroup likely contains overlapping patients with the previous report, and the results were similar (i.e., greater improvements were reported in those patients who had a total of five treatments).

## **Nonrandomized Studies**

A 2008 retrospective cohort study assessed the incremental value of RFA of the tongue in combination with UPPP.<sup>[21]</sup> All patients with both palatal and retroglossal obstruction, an RDI between 5 and 50, and no previous OSA surgery were included in the study. Seventy-five patients meeting the inclusion criteria had been treated with UPPP during the three year period, 38 had UPPP alone, 37 had UPPP plus RFA. The groups were comparable for age, sex, BMI, AHI, and mean arterial oxygen saturation (SaO<sub>2</sub>); however, no details were provided regarding the choice of procedure. With surgical success rate defined as more than 50% reduction of the AHI and AHI below 20, the success rate was 42% with UPPP alone and 49% with RFA (not significantly different). Two patients had an additional RFA treatment. No major complications were observed. The study concluded that the addition of RFA to UPPP resulted in only limited improvement, but there was no major downside to it.

Two earlier case series have been published by Steward (2005) and Stuck (2004) on the use of radiofrequency ablation of both tongue base and soft palate tissue, referred to as a

combined or multi-level radiofrequency tissue ablation technique.<sup>[22, 23]</sup> Both case series reported significant improvements, including reductions in mean respiratory disturbance and apnea-hypopnea indexes, and in one case series these improvements persisted for a median of 23 months. However, both case series are limited by size, including 29 and 20 patients, respectively, and potential selection bias among the included participants. In addition, the ability to detect true long-term efficacy of this treatment is limited by the case series study design with lack of control group.

## **Radiofrequency Volumetric Tissue Reduction of the Tongue Base or Palatal Tissues Section Summary**

The evidence for the use of radiofrequency volumetric tissue reduction of the tongue base or palatal tissues for the treatment of obstructive sleep apnea or upper airway resistance syndrome includes two systematic reviews, three randomized controlled trials, and three non-randomized studies. The considerable heterogeneity of outcomes tested across studies does not allow for conclusions about the potential benefit of these procedures. Additional appropriately controlled studies are needed to inform the clinical outcomes of these procedures alone or in addition to standard of care, as well as to evaluate the long-term benefits of these procedures.

### **TONGUE BASE SUSPENSION PROCEDURES**

#### **Systematic Reviews**

In 2013, Handler reported a systematic review of tongue suspension versus hypopharyngeal surgery for the treatment of OSA.<sup>[24]</sup> The review included 27 studies reporting on four separate procedures; tongue suspension alone, tongue suspension + UPPP, genioglossus advancement (GA) + UPPP, and genioglossus advancement + hyoid suspension (GAHM) + UPPP. A successful treatment was defined as a 50% decrease in the RDI or AHI and a postoperative RDI or AHI less than 20. Tongue suspension alone (six studies, 82 patients) had a success rate of 36.6%, while the success rate of tongue suspension + UPPP (eight studies, 167 patients) was 62.3%. A success rate of 61.1% was found for GA + UPPP (seven studies, 151 patients) and for GAHM + UPPP (12 studies, 467 patients). The adverse effects of tongue suspension appear to be milder than GA or GAHM and are reversible. Most of the studies identified in this review were level IV evidence (case series).

#### **Randomized Controlled Trial**

One level II RCT by Fernandez-Julian (2009) included in the systematic review compared two tongue base surgeries (RFA or tongue-base suspension) combined with UPPP for moderate to severe sleep apnea (AHI  $\geq 15$ ).<sup>[18]</sup> In the tongue suspension plus UPPP group (n=28), the mean AHI decreased from 33.1 to 15.1 events per hour. The success rate for the combined procedure (defined as a  $\geq 50\%$  reduction, final AHI  $< 15$ , and ESS  $< 11$ ) was 57.1%, compared with a success rate of 51.7% in the UPPP plus RFA group (p=0.79). BMI was the main predictor of success, with a success rate for tongue base suspension plus UPPP of only 10% in patients with a BMI between 30 and 35 kg/m<sup>2</sup>. Morbidity and complications were higher with the tongue suspension procedure compared with RFA.

#### **Nonrandomized Studies**

In 2013, Li conducted a nonrandomized comparative study to evaluate the use of the Repose system in conjunction with UPPP to treat patients with obstructive sleep apnea hypopnea

syndrome (OSAHS) caused by suspected glossoptosis.<sup>[25]</sup> Seventy-eight patients with OSAHS caused by suspected glossoptosis were non-randomly divided into two groups. The 45 patients in the first group received UPPP and tongue-base suspension (Repose). The 33 patients in the second group received UPPP alone. Follow-up was conducted over six months, and polysomnography was used to determine the effects of treatment. Follow-up results at six months revealed that the degree of improvement in patients treated with UPPP + Repose was significantly greater than that seen in patients treated with UPPP alone. In the UPPP + Repose group, 17 patients were cured, 23 showed marked improvement, and five did not improve. In the UPPP alone group, one patient was cured, 16 showed marked improvement, and 16 did not improve. The marked improvement rates of the two groups were 88.9 and 51.5 %, respectively, a significant difference.

In a 2010 multicenter, prospective case series, Woodson assessed the safety and effectiveness of an adjustable lingual suspension device (Advance System) for treating OSA.<sup>[26]</sup> 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.

In 2002, Miller 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.<sup>[27]</sup> 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. 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.

In 2000, DeRowe performed minimally invasive technique for tongue-base suspension with the Repose system in 16 patients with sleep-disordered breathing.<sup>[28]</sup> 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. Similar improvements were reported in other small case series (n=8-14 patients with OSA) who underwent the same procedure.<sup>[29-31]</sup>

## **Tongue Base Suspension Procedures Section Summary**

Evidence for the tongue base suspension procedures for the treatment of sleep apnea or upper airway resistance syndrome includes one systematic review, one randomized controlled trial, and four non-randomized studies. These studies report low success rates of the procedure, particularly in obese individuals, and adverse events including wound infection, edema, pain, and tissue anchor barb fractures are reported. Long-term outcomes of the procedure are not well characterized. Additional studies with longer end-points including those addressing safety and efficacy are needed.

## **LASER-ASSISTED PALATOPLASTY**

### **Systematic Reviews**

Wischhusen (2019) published a SR evaluating the complications and side effects of laser-assisted uvulopalatoplasty (LAUP) across 42 studies (N=3,093). Mean follow-up was 16.1 months (median six months, range of 0.5 – 134 months).<sup>[32]</sup> Across all 42 studies, the total number of LAUP complications based on a population of 1,000 patients with a 95% CI was reported as  $255.71 \pm 23.33$ . The authors also calculated relative risk of specific complications compared to published population studies and found significant effects for complications of globus sensation and velopharyngeal (VP) insufficiency with 95% CI of 1.07–2.06 and 1.29–3.94, respectively. In the four studies with the longest follow-up duration with a mean of 100.5 months, these complications were 12.2% and 10.8%, respectively, suggesting that these may be long-term complications of the procedure. The authors conclude “based on the findings of this systematic review, we recommend that LAUP be performed with caution using the tissue-sparing approach or avoided altogether, given the potential for complications identified in the current literature.”

### **Randomized Controlled Trials**

Ferguson (2003) reported a trial that randomized 45 subjects with mild-to-moderate sleep apnea (defined as an AHI ranging between 10-27 per hour) to either uvulopalatoplasty (LAUP) or no treatment.<sup>[11]</sup> The LAUP procedure was repeated at 1- to 2-month intervals until either the snoring was significantly reduced, no more tissue could safely be removed, or the patient refused further procedures. The primary outcome measurement was the reduction in AHI in the LAUP group versus the control group. An AHI of less than 10 was considered a successful treatment. In the treatment group, 24% were considered treatment successes and 76% were failures. In the control group (who received no therapy), 16.7% were considered treatment successes. The authors concluded that LAUP can be effective in some patients, but the reduction in AHI and the level of symptomatic improvement were minor overall.

### **Nonrandomized Studies**

In 1995, Walker prospectively evaluated the outcomes of 65 patients who underwent LAUP for the treatment of OSA.<sup>[33]</sup> Of the 65 OSAS patients treated with LAUP, postoperative polysomnograms were obtained in 33 patients (51%). Surgical success was achieved in 16 (48%) of the 33 patients. However, seven patients (21%) had repeat polysomnograms that were worse than their preoperative polysomnograms, and five patients (15%) had no significant change.

## **CAUTERY-ASSISTED PALATAL STIFFENING OPERATION**

### **Systematic Reviews**

Llewellyn (2018) published a SR with meta-analysis of outcomes for cautery-assisted palatal stiffening operation (CAPSO) as a treatment for adult OSA. This SR included eight studies (N=307) conducted in adult patients with sleep disordered breathing.<sup>[34]</sup> Additional inclusion criteria for the SR were: “outcomes for sleep study information, snoring and/or sleepiness; anterior palatoplasty or palatal stiffening operation or CAPSO or modified CAPSO with or without tonsillectomy/expansion pharyngoplasty (plication of palatopharyngeus);” and no other surgical procedures performed at the same time. Among these studies, four were considered to have high risk of bias in patient selection per QUADAS-2. The authors reported the following improvements (mean  $\pm$  standard deviation [M  $\pm$  SD] events per hour, percent change) in AHI: CAPSO alone (N=80 patients), (16.8  $\pm$  11.9) to (9.9  $\pm$  10.9), a 41.1% decrease; mixed CAPSO with/without tonsillectomy (N=92), (24.8  $\pm$  12.6) to (10.6  $\pm$  9.5), a 61.7% decrease; CAPSO with expansion pharyngoplasty (N=78), (26.3  $\pm$  17.7) to (12.6  $\pm$  5.8), a 52.1% decrease. The authors also reported the following improvement in lowest oxygen saturation (LSAT): CAPSO alone (N=90), 5.4 point improvement; mixed CAPSO with/without tonsillectomy (N=77), 10.6 point improvement; and CAPSO with expansion pharyngoplasty (N=78), 5.2 point improvement. Although the authors reported effect sizes for pre- and post-surgery outcomes across all data, for none of the above analyses evaluating effects of CAPSO alone or in combination with other interventions were assessments of statistical significance (p values) reported. This SR included studies by Mair (2000) and Pang (2007), which focused on patients with simple snoring (AHI <5) or mild sleep apnea (AHI <15).<sup>[35, 36]</sup> A study with long-term follow-up reported in this SR found that 38% of patients with mild to moderate OSA had globus sensation and inability to clear phlegm 2 years after the operation.<sup>[37]</sup> Future RCTs evaluating the specific and long-term benefit of CAPSO in OSA are needed.

### **Randomized Controlled Trials**

No additional RCTs beyond those addressed in the SR above on the use of cautery-assisted palatal stiffening operation in the treatment of OSA or UARS have been identified.

## **PALATAL IMPLANTS**

### **Systematic Reviews**

No SRs for the use of palatal implants for the treatment of OSA or UARS have been identified.

### **Randomized Controlled Trials**

In 2012, Maurer reported a randomized double-blind, sham-controlled trial of the Pillar palatal implant in 20 patients with mild to moderate OSA because of palatal obstruction.<sup>[38]</sup> At 90 days, the AHI in the treatment group improved from 19.1 to 8.2 events per hour and lowest oxygen saturation improved from 82.8% to 88.3%. These measures did not improve significantly in the control group, and there was no significant difference in outcomes between the implant and control groups in this small trial. The ESS did not improve significantly in either group.

In a 2008 trial by Steward, 100 patients with mild to moderate OSA and suspected retropalatal obstruction were randomly assigned to palatal implants or sham placebo.<sup>[39]</sup> Patients with BMI greater than 32 kg/m<sup>2</sup> were excluded from the study. About 1000 patients were evaluated to identify the 100 study patients. At three-month follow-up, the average AHI increased in both groups from a baseline of about 17, although the increase was greater in the placebo group (8.9 vs 2.9, respectively). A reduction in AHI by at least 50% or to below 20 was more common



in the implant group (26% vs 10%, respectively;  $p=0.05$ ). Improvement in ESS did not differ from that of sham ( $p=0.62$ ). Partial implant extrusion occurred in two patients (4%).

In 2008, Friedman reported an industry-sponsored randomized double-blind, sham-controlled trial of palatal implants in 62 patients with symptoms of OSA.<sup>[40]</sup> Other inclusion criteria included: Friedman tongue position I, II, or III; diagnosis of mild to moderate OSA (AHI  $\geq 5$  and  $<40$ ) on baseline polysomnography (PSG); a soft palate of 2 cm or more but less than 3.5 cm; and BMI less than 32 kg/m<sup>2</sup>. AHI at baseline was 23.8 events per hour in the implant group and 20.1 in controls. Seven patients did not return for repeat PSG and were considered treatment failures in the intention-to-treat analysis. At three-month follow-up, the AHI improved to 15.9 events per hour in the implant group but did not change significantly in the controls (21.0). The ESS improved from 12.7 to 10.2 in the implant group and did not change significantly in the controls (11.7 to 11.1). With success defined as an AHI reduction of 50% or more and AHI less than 20, palatal implantation resulted in the successful treatment of 41.9% of implanted patients compared with 0% of controls. Two patients had partial implant extrusion.

### **Nonrandomized Studies**

Neruntarat (2011) reported a case series with a minimum of 24-month follow-up.<sup>[41]</sup> This study included 92 patients with mild to moderate OSA (AHI  $\leq 30$  with daytime sleepiness or disturbed sleep) who had received palatal implants after failed medical management. At baseline, the mean AHI was 21.7 events per hour, and the lowest oxygen saturation was 87.4%. At mean 28.9-month follow-up, the AHI had decreased to 10.8, and the lowest oxygen saturation improved to 89.2%. Sleep efficiency improved from 80.6% to 87.2%, and the ESS score improved from a mean of 12.3 to 7.9. Implant extrusion occurred in seven patients (7.6%), and palatal abscess occurred in one patient (1.1%). Confounding factors, such as significantly lower BMI in “responders” may have affected the interpretation of the efficacy of this procedure in this patient population.

Walker published 90-day and 15-month follow-up from a multicenter study on palatal implants (Pillar System) in 63 subjects.<sup>[42, 43]</sup> The AHI decreased from a baseline of 25 to 22 in the 53 patients (84%) who were evaluated at 90 days. Twenty-two patients (35%) were available for the follow-up study; 13 had shown a decrease in AHI (from a baseline of 20 to 13) at 90 days. Of these, 10 (77% of the 13) maintained the decrease at 15 months. The nine patients whose AHI had not improved at 90 days had no subsequent improvement at the extended follow-up. Mean snoring was rated as eight at baseline (visual analog scale), and 4 at both 90 days and 15 months. Subjective daytime sleepiness measured by the ESS was reduced at 90 days (11 to 7) but returned to a score of 11 at the longer follow-up. In addition to the very large loss to follow-up, questions remain about the clinical significance of a three- to seven-point improvement in AHI.

In a prospective study, Nordgard (2007) assessed the long-term effectiveness of palatal implants for treatment of mild-to-moderate OSA.<sup>[44]</sup> A total of 26 referred patients with a pre-treatment AHI of 10 to 30 and a BMI of less than or equal to 30, representing an extended follow-up of a subset of 41 patients enrolled in previous short-term trials were included. Twenty-one of 26 patients (80.8 %) experienced a decrease in AHI. Fifteen of 26 patients (57.7 %) had a follow-up AHI less than 10 at one year, whereas 13 patients (50 %) had a 50 % or greater reduction to an AHI less than 10 at one year. Mean AHI was reduced from 16.5 +/- 4.5 at baseline to 12.5 +/- 10.5 at three months ( $p < 0.014$ ) and to 12.3 +/- 12.7 at one year ( $p < 0.019$ ). The authors concluded that patients initially responding to palatal implants with

improved AHI maintained improvement through long-term follow-up at one year. The main limitation of this study was its small sample size. The authors noted that additional studies with longer follow-up would be appropriate.

Nordgard (2006) conducted a prospective nonrandomized study of 25 patients with untreated OSA with an AHI of 10–30, as determined by preoperative PSG, and BMI  $\leq$  30.<sup>[45]</sup> Three permanent implants were placed in the soft palate of each patient in an office setting under local anesthesia. A repeat PSG showed a mean decrease in AHI from 16.2 to 12.1 for the study group. Twenty of 25 patients demonstrated a reduced AHI, and 12 of 25 patients demonstrated an AHI of 10 or less 90 days post-implant. The mean ESS score decreased from 9.7 to 5.5. The authors concluded that palatal implants can significantly improve AHI and other sleep-related parameters in patients with mild to moderate OSA and BMI  $\leq$  30, with short-term results comparable to those reported for UPPP. The authors acknowledged the lack of long-term outcomes in this study and the limited number of patients. As with other palatal procedures, reduction in effectiveness over time may be expected. The authors further concluded that while short-term durability and effectiveness have been established, longer-term research needs to be conducted.

In a retrospective, nonrandomized, controlled study, Friedman (2006) evaluated the Pillar implant system alone and in combination with other procedures for treatment of mild-to-moderate OSA/hypopnea syndrome (OSAHS).<sup>[46]</sup> A total of 125 patients who had mild-to-moderate OSAHS were assigned to palatal implantation alone (palatal group, n=29), or in combination with other procedures. Most of the procedures other than palatal implantation were not defined clearly. After a mean follow-up of eight 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 seven (24%) palatal group patients and 43 (34%) of all patients were "cured." One of the study limitations was that many patients had an AHI  $<$  20 at baseline, particularly in the Palatal Group, which had a baseline AHI of 13.8.

Three other small, uncontrolled studies have been performed to evaluate the Pillar Palatal Implant System for mild-to moderate OSA.<sup>[47, 48]</sup> 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 one year of follow-up; however, these studies do not provide reliable evidence of efficacy since they did not involve any control or comparison groups.

### **Palatal Implants Section Summary**

The literature on palatal implants consists of three moderately-sized RCTs and additional case series with medium-term follow-up. Evidence from sham-controlled trials shows a statistically significant but modest reduction in AHI and improvement in lowest oxygen saturation compared with placebo, with limited effects on daytime sleepiness. Additional studies are needed to determine whether there is a defined subset of patients who might benefit from this procedure. Studies with longer term follow-up are also needed to evaluate the potential for extrusion of the implants at longer time intervals.

## **PRACTICE GUIDELINE SUMMARY**

### **THE US DEPARTMENT OF VETERANS AFFAIRS AND THE DEPARTMENT OF DEFENSE**

The 2019 US Department of Veterans Affairs and Department of Defense (VA/DoD) Guideline for the Management of Chronic Insomnia Disorder and Obstructive Sleep Apnea provide the following recommendations regarding surgical treatment of OSA:<sup>[49]</sup>

*For patients with severe obstructive sleep apnea who cannot tolerate or are not appropriate candidates for other recommended therapies, we suggest evaluation for alternative treatment with maxillomandibular advancement surgery. (Strength of recommendation: weak for. Category: new recommendation following review of the evidence)*

## **AMERICAN ACADEMY OF OTOLARYNGOLOGY - HEAD AND NECK SURGERY**

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) has published a number of consensus-based policy statements on various techniques for surgical management of obstructive sleep apnea.<sup>[4, 50-54]</sup> AAO-HNS position statements, by definition are “based on an informal process of expert or committee consensus that draws upon best available evidence and quality products.”, thus each of the position statements may be supported to varying degrees by evidence. Procedures the AAO-HNS supports as effective and not considered investigational when part of a comprehensive approach in the medical and surgical management of adults with OSA include palatal advancement, uvulopalatopharyngoplasty, uvulopalatoplasty (including laser assisted and other techniques), genioglossal advancement, hyoid myotomy, midline glossectomy, tongue suspension, and maxillary and mandibular advancement.

No evidence-based practice guidelines from the AAO-HNS were identified.

## **SUMMARY**

There is enough research to suggest that uvulopalatopharyngoplasty (UPPP) and its variants, hyoid suspension, mandible osteotomy, partial glossectomy, and maxillofacial surgeries such as maxillo-mandibular advancement (MMA) may improve health outcomes for some patients with obstructive sleep apnea (OSA) or airway resistance syndrome (UARS). These procedures have become a standard of care and may therefore be considered medically necessary when the policy criteria are met.

There is not enough research to support surgery as first-line treatment of obstructive sleep apnea (OSA) or upper airway resistance syndrome (UARS). Therefore, surgical treatments may be considered medically necessary only after failed medical therapy, including nasal continuous positive airway pressure (PAP) and a custom-made mandibular repositioning appliance. In addition, surgical treatments including uvulopalatopharyngoplasty (UPPP) and its variants, hyoid suspension, mandible osteotomy, partial glossectomy, and maxillofacial surgeries such as maxillo-mandibular advancement (MMA) are considered not medically necessary when criteria are not met.

There is not enough research to determine the safety and efficacy of surgical interventions including but not limited to uvulectomy, and minimally invasive surgical procedures such as laser-assisted uvuloplasty (LAUP), radiofrequency tongue base or tissue volume reduction, palatal stiffening procedures, and palatal implants. The use of these interventions is

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considered investigational for the treatment of obstructive sleep apnea (OSA) or airway resistance syndrome (UARS).

Snoring in the absence of clinically significant obstructive sleep apnea (OSA) is not considered a medical condition. Therefore, any surgical intervention, including but not limited to uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatoplasty (LAUP), radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures for snoring alone is considered not medically necessary.

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## CODES

**NOTE:** There is no specific CPT code for the tongue base reduction procedure. The most appropriate code to use is 41599 (unlisted procedure) or 41530. 41120 (partial glossectomy) describes a surgical resection and is not the appropriate code to use for submitting claims for tongue base reduction.

Codes	Number	Description
CPT	21121	Genioplasty; sliding osteotomy, single piece
	21122	Genioplasty; sliding osteotomies, two or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)
	21141	Reconstruction midface, LeFort 1; single piece, segment movement in any direction (eg, for Long Face Syndrome), without bone graft

<b>Codes</b>	<b>Number</b>	<b>Description</b>
	21145	Reconstruction midface, LeFort 1; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)
	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
	21685	Hyoid myotomy and suspension
	41120	Glossectomy; less than one-half tongue
	41512	Tongue base suspension, permanent suture technique
	41530	Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session
	41599	Unlisted procedure, tongue, floor of mouth
	42140	Uvulectomy, excision of uvula
	42145	Palatopharyngoplasty (eg, Uvulopalatopharyngoplasty, Uvulopharyngoplasty)
	42160	Destruction of lesion, palate or uvula (thermal, cryo, or chemical)
	42299	Unlisted procedure, palate, uvula
HCP	S2080	Laser-assisted uvulopalatoplasty (LAUP)

<b>Appendix 1: Procedures for the Diagnosis of Sleep Disordered Breathing</b>	
<b>Polysomnography (PSG)</b>	<p>Full night PSG consists of five to eight hours of monitoring, supervised by a sleep technician, while the patient sleeps. It is performed in a sleep lab and involves the following monitoring modalities: electroencephalogram (EEG) (to stage sleep and detect arousals), electro-oculogram (EOG) (to detect arousal and REM sleep) submental electromyogram, (EMG), electrocardiogram (EKG), two-leg EMG, respiratory airflow and effort (to detect apnea), snoring, oxygen saturation, time and position. In addition, a full night PSG may include additional monitoring modalities as indicated, such as esophageal pressure monitoring, blood pressure monitoring, carbon dioxide trends, and pulse transit time.</p> <p>The first three elements listed above (EEG, submental electromyogram, and electro-oculogram) are required for sleep staging. By definition, a polysomnogram always includes sleep staging, while a “sleep study” does not include sleep staging. The actual components of the study will be dictated by the clinical situation. Typically, the evaluation of obstructive sleep apnea would include respiratory airflow and effort, electro-oculogram, and oxygen desaturation. An EEG may not be considered necessary to evaluate OSA, although it is required to evaluate UARS, REM sleep behavior disorder (RBD), narcolepsy or other sleep disturbances.</p>
<b>Split Night Polysomnography</b>	<p>A split night study utilizes the first two or three hours for evaluating the presence of sleep apnea and the second half to titrate and adjust CPAP. The same monitoring modalities used in full night PSG are used in split night study. In patients with severe obstructive sleep apnea, a reliable assessment of the respiratory disturbance index is possible with a partial night study. Half night study for CPAP titration is reliable in selected cases of obstructive sleep apnea.</p> <p>Split night studies are appropriate in patients with severe sleep apnea syndrome. The decision to conduct a split night study depends on the technical skill and experience of the staff, the initial sleep latency period, the severity and frequency of respiratory events and patient compliance. Careful</p>



<b>Appendix 1: Procedures for the Diagnosis of Sleep Disordered Breathing</b>	
	<p>patient selection and education is required to conduct a successful split night study.</p>
<b>Home Sleep Apnea Testing Device (HSAT Device)</b>	<p>Per the 2017 American Academy of Sleep Medicine (AACM) Clinical Practice Guideline for diagnostic testing for adult obstructive sleep apnea, home sleep apnea testing with a technically adequate device may be used for the diagnosis of obstructive sleep apnea (OSA) in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA.<sup>[1]</sup></p> <p>An uncomplicated patient is defined by the absence of:</p> <ol style="list-style-type: none"> <li>1. Conditions that place the patient at increased risk of non-obstructive sleep-disordered breathing (e.g., central sleep apnea, hypoventilation and sleep related hypoxemia). Examples of these conditions include significant cardiopulmonary disease, potential respiratory muscle weakness due to neuromuscular conditions, history of stroke and chronic opiate medication use.</li> <li>2. Concern for significant non-respiratory sleep disorder(s) that require evaluation (e.g., disorders of central hypersomnolence, parasomnias, sleep related movement disorders) or interfere with accuracy of HSAT (e.g., severe insomnia).</li> <li>3. Environmental or personal factors that preclude the adequate acquisition and interpretation of data from HSAT.</li> </ol> <p>An increased risk of moderate to severe OSA is indicated by the presence of excessive daytime sleepiness and at least two of the following three criteria: habitual loud snoring, witnessed apnea or gasping or choking, or diagnosed hypertension.</p> <p>HSAT is to be administered by an accredited sleep center under the supervision of a board-certified sleep medicine physician, or a board-eligible sleep medicine provider.</p> <p>A single HSAT recording is conducted over at least one night.</p> <p>A technically adequate HSAT device incorporates a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else peripheral arterial tone (PAT) with oximetry and actigraphy.</p> <p>A technically adequate diagnostic test includes a minimum of 4 hours of technically adequate oximetry and flow data, obtained during a recording attempt that encompasses the habitual sleep period.</p> <p>If a single HSAT is negative, inconclusive, or technically inadequate, polysomnography should be performed for the diagnosis of OSA.</p>
<b>SNAP™ Testing</b>	<p>The SNAP testing system is a reflective acoustic device marketed as a screening and analysis system to locate the source of snoring and detect sleep apnea conditions.</p>
<b>Multiple Sleep Latency Tests (MSLT)</b>	<p>The MSLT measures the speed of falling asleep under conditions that favor sleep, in a series of 20-minute trials during the patient's habitual periods of wakefulness. MSLT is the preferred method of establishing the presence of true physiological sleepiness but is accurate only if following strict protocols.</p>

<b>Appendix 1: Procedures for the Diagnosis of Sleep Disordered Breathing</b>	
	MSLT is used in patients with complaints of irresistible daytime sleepiness suggestive of narcolepsy.
<b>Maintenance of Wakefulness Test (MWT)</b>	The patient is monitored during the usual periods of wakefulness but the patient is instructed not to fall asleep as a test of the patient's ability to stay awake. It may be used to evaluate the safety of drivers and their ability to stay alert.
<b>Radiologic Studies</b>	Radiologic images of the head and neck for anatomic abnormalities include MRI, CT scan, and cephalometry. Such studies are intended to assess for hypopharyngeal obstruction or other suspected pathology that might explain the symptoms associated with sleep disordered breathing.
<b>Endoscopic Studies</b>	Nasopharyngeal and laryngeal endoscopic measurements of structure and function of the upper airway are used in selected patients with suspected abnormal anatomy as an aid in the diagnosis of OSA or in the management of complications of treatment.
<b>Epworth Sleepiness Scale</b>	Excessive daytime sleepiness is predominantly a subjective symptom. The Epworth sleepiness scale is a self-administered questionnaire, performed as part of the clinical evaluation, that asks patients their likelihood of falling asleep in eight situations ranked from 0 (would never fall asleep) to 3 (high chance of dozing). The numbers are then added together to give a global score between 0 and 24. A value of 10 or below is considered normal.
<b>Apnea-Hypopnea Index (AHI); Respiratory Disturbance Index (RDI)</b>	Apnea is defined as the cessation of respiration for at least 10 seconds. Hypopnea is a reduction but not cessation of air exchange. Apneic and hypopneic events are combined into the apnea-hypopnea index (AHI). In turn the AHI is often referred to as the respiratory disturbance index (RDI), although more recently the RDI has been redefined by some physicians to include EEG arousals in addition to apneic and hypopneic events. An AHI of greater than or equal to 20 is typically considered moderate OSA, and AHI of greater than 50 is considered severe OSA. An increase in mortality is associated with an AHI of greater than 15.
<b>Polysomnography (PSG)</b>	<p>Full night PSG consists of five to eight hours of monitoring, supervised by a sleep technician, while the patient sleeps. It is performed in a sleep lab and involves the following monitoring modalities: electroencephalogram (EEG) (to stage sleep and detect arousals), electro-oculogram (EOG) (to detect arousal and REM sleep) submental electromyogram, (EMG), electrocardiogram (EKG), two-leg EMG, respiratory airflow and effort (to detect apnea), snoring, oxygen saturation, time and position. In addition, a full night PSG may include additional monitoring modalities as indicated, such as esophageal pressure monitoring, blood pressure monitoring, carbon dioxide trends, and pulse transit time.</p> <p>The first three elements listed above (EEG, submental electromyogram, and electro-oculogram) are required for sleep staging. By definition, a polysomnogram always includes sleep staging, while a "sleep study" does not include sleep staging. The actual components of the study will be dictated by the clinical situation. Typically, the evaluation of obstructive sleep apnea would include respiratory airflow and effort, electro-oculogram, and oxygen desaturation. An EEG may not be considered necessary to</p>

<b>Appendix 1: Procedures for the Diagnosis of Sleep Disordered Breathing</b>	
	evaluate OSA, although it is required to evaluate UARS, REM sleep behavior disorder (RBD), narcolepsy or other sleep disturbances.
<b>Split Night Polysomnography</b>	<p>A split night study utilizes the first two or three hours for evaluating the presence of sleep apnea and the second half to titrate and adjust CPAP. The same monitoring modalities used in full night PSG are used in split night study. In patients with severe obstructive sleep apnea, a reliable assessment of the respiratory disturbance index is possible with a partial night study. Half night study for CPAP titration is reliable in selected cases of obstructive sleep apnea.</p> <p>Split night studies are appropriate in patients with severe sleep apnea syndrome. The decision to conduct a split night study depends on the technical skill and experience of the staff, the initial sleep latency period, the severity and frequency of respiratory events and patient compliance. Careful patient selection and education is required to conduct a successful split night study.</p>

<b>Appendix 2: Nonsurgical Devices for Treatment of OSA or UARS</b>	
<b>CPAP</b>	Nasal or oral continuous positive airway pressure (CPAP) or auto-titrating continuous positive airway pressure (APAP) is continuous positive airway pressure applied through the nose or via oral appliance. It is delivered by a flow generator through a mask to supply a pressure level sufficient to keep the upper airway patent. The pressure used is determined individually with a range of three to 15 centimeters of water.
<b>BiPAP®</b>	<p>Bi-level respiratory assist device delivers alternating levels of positive airway pressure instead of the continuous pressure applied by CPAP.</p> <p>A bi-level positive airway pressure device with back-up rate feature is a ventilation support system. These devices are in the FDA category of non-continuous ventilator, and as such, are primarily intended to augment patient ventilation.</p> <p>The term BiPAP® is a registered trademark of <i>Respironics Inc.</i>, but is widely used to describe any bi-level positive airway pressure device as described above.</p>
<b>APAP</b>	Auto-adjusting CPAP (APAP) is a more recent technology which alternates airway pressure between exhalation and inhalation on a breath-by-breath basis. With the C-Flex™ (Respironics, Inc) airway pressure is reduced during early exhalation in proportion to the patient's expiratory flow rate. Pressure is then increased again toward the end of exhalation when airway collapse is most likely. Unlike BiPAP which delivers a static lower expiratory pressure, the C-Flex varies the pressure within the expiratory phase.
<b>Oral Appliances (OA)</b>	OA for the treatment of sleep disordered breathing are devices worn in the mouth during sleep to maintain a patent airway by raising the uvula, depressing the tongue, and/or advancing the mandible (in which case they are also known as mandibular advancement devices [MAD]). Commercially available devices are usually custom-molded or custom-fitted for the individual patient by a qualified dental health professional trained and

## Appendix 2: Nonsurgical Devices for Treatment of OSA or UARS

experienced in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures. According to the American Academy of Sleep Medicine, dental management of patients with oral appliances should be overseen by practitioners who trained in sleep medicine and sleep related breathing disorders.<sup>[55, 56]</sup> Oral appliances can range from simple retaining devices, to adjustable, hinged, or two-piece designs. Some designs can be used in conjunction with a CPAP device (e.g., OPAP®).

*Date of Origin: March 2009*