

Surgeries for Snoring and Obstructive Sleep Apnea Syndrome in Adults

Effective: February 1, 2019

Next Review: January 2020

Last Review: January 2019

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 nonsurgical therapies for obstructive sleep apnea fail, surgical interventions such as uvulopalatopharyngoplasty (UPPP) and mandibular-maxillary advancement (MMA) may be considered.

MEDICAL POLICY CRITERIA

Notes:

- Contract language takes precedent over medical policy. Some member contracts have specific benefit limitations for orthognathic surgery.
- **Criteria I. and II. apply to adult and pediatric patients.** Surgical treatment of obstructive sleep apnea and upper airway resistance syndrome in **pediatric patients** may be considered **medically necessary** if neither Criterion I. nor Criterion II. apply.
- **Criteria III. and IV. only apply to adult patients.**
- For the purposes of this policy, adult patient is defined as age 18 years and older and pediatric patient is defined as age 17 years and younger.

Adult and Pediatric Patients

- I. Surgical treatment of snoring in the absence of documented obstructive sleep apnea in adult and pediatric patients is considered **not medically necessary**.
- II. Surgical treatment of obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS) in adult and pediatric patients is considered **investigational** including, but not limited to the following:
 - A. Implantable hypoglossal nerve stimulators when Criteria III.A.-C. are not met
 - B. Laser-assisted palatoplasty (LAUP) or volumetric tissue reduction
 - C. Palatal stiffening procedures, including but not limited to the following:
 1. Cautery-assisted palatal stiffening operation (CAPSO)
 2. Injection of sclerosing agent (also known as snoreplasty)
 3. Implantation of palatal implants (also known as the pillar procedure)
 - D. Radiofrequency volumetric tissue reduction of the tongue base or palatal tissues
 - E. Tongue base suspension procedures, including but not limited to the AIRvance™ and the Encore™ tongue suspension systems
 - F. Uvulectomy

Adult Patients

- III. Surgical procedures for the treatment of obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS) in adult patients may be considered **medically necessary** when all of the criteria below (A, B, C, **and** D) are met:
 - A. There is documentation of a sleep study performed within the last 3 years; and
 - B. 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. Obstructive sleep apnea (OSA) that is clinically significant OSA is 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. History of stroke
 - v. Obesity
 - vi. Diabetes and glucose intolerance
 - vii. 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.
- C. 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
 2. Avoidance of alcohol and sedative drugs
 3. Nasal CPAP: An adequate CPAP trial must include documentation of one of the following:
 - a. A minimum of 4 hours per night for 3 weeks of CPAP usage, to include as necessary, reasonable attempts to address any medical, mechanical, or psychological problems associated with CPAP (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)
 - b. For patients with severe psychological aversion to CPAP, reasonable attempts have been made to complete a conventional desensitization program (see below).
 - i. 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.
 - ii. For patients with severe psychological aversion to CPAP, monitoring during desensitization programs (e.g., PAP-NAP) is considered **not medically necessary**. This monitoring may be reported using CPT code 95807.
- D. Both of the following conditions are met:
1. The Criteria III.A.-C. above are met; and
 2. One or more of the following procedures are requested:
 - a. Hyoid myotomy and suspension
 - b. Implantable hypoglossal nerve stimulator
 - c. Mandible osteotomy with or without genioglossus advancement
 - d. Mandibular-maxillary advancement (MMA) with documentation of hypopharyngeal obstruction

e. Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty [UPPP], uvulopharyngoplasty)

f. Partial Glossectomy

IV. Surgical treatment of obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS) in adult patients is considered **not medically necessary** when criteria III. are not met.

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

POLICY GUIDELINES

SUBMISSION OF DOCUMENTATION

It is critical that the list of information below is submitted for review to determine if the 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
- CPAP Trial results
- Sleep Study results

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

BACKGROUND

OBSTRUCTIVE SLEEP APNEA (OSA)

Obstructive sleep apnea syndrome is an important syndrome associated with increased risk of heart failure and potential increase in overall morbidity and mortality.^[1] OSA is defined as repeated periods of complete airway obstruction (apnea) lasting at least 10 seconds during sleep. Hypopnea, partial airway obstruction with at least 30% reduction in airflow for 10 seconds or more, may also be present. When the sequence of breaths does not meet criteria for an apnea or hypopnea, but lasts at least 10 seconds and is characterized by either increasing respiratory effort or an arousal from sleep, this is scored as a respiratory event related arousal (RERA). Inadequate oxygen intake during these episodes results in a drop in oxygen saturation, which stimulates a brief awakening that is usually accompanied by gasping until the oxygen saturation rises. This cycle usually repeats throughout the night.

A polysomnogram performed in a sleep laboratory is considered the gold standard test used to diagnose OSA. 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 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.

According to the American Academy of Sleep Medicine, the following AHI/RDI levels are used for the diagnosis of OSA:^[2]

- Mild OSA: AHI between 5 and 15 per hour
- Moderate OSA: AHI \geq 15 per hour
- Severe OSA: AHI \geq 30 per hour

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.^[2,3] 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.

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 medical treatments for OSA or UARS have failed. Conventional surgeries for OSA include uvulopalatopharyngoplasty (UPPP) and a variety of maxillofacial surgeries such as mandibular-maxillary advancement (MMA).

Uvulopalatopharyngoplasty (UPPP)

UPPP involves surgical modification of the oropharynx and/or velopharynx by resection of the associated structures (soft palate, uvula, and associated muscles).^[4,5] 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

Radiofrequency ablation of the soft palate/volumetric reduction of the tongue base (RFTBR)

Radiofrequency energy is used to produce thermal lesions within the tissues, rather than using a laser to ablate the tissue surface, which may be painful. These procedures reduce the volume of soft tissue and stiffen the tissue due to the creation of a submucosal scar; and may also be referred to as a 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 bone screw. 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.

Implantable hypoglossal nerve stimulators

Hypoglossal nerve stimulation involves the surgical implantation of a subcutaneous generator in the upper chest and an electrode tunneled from the generator to the hypoglossal nerve. The patient uses a hand-held remote to activate the device just prior to sleep and to turn it off upon waking. Some have sensors detect inspiratory efforts and the hypoglossal nerve is stimulated in a synchronized fashion. This stimulation is intended to maintain muscle tone of the tongue base to prevent airway occlusion.

Stimulation systems such as the Inspire II Upper Airway Stimulation System include respiratory sensing leads that permit intermittent stimulation during inspiration. Stimulation parameters are titrated during an in-laboratory polysomnography and can be adjusted by the patient during home use. The device is turned on only during sleep periods.

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.

The *Inspire® II Upper Airway Stimulation System* (Inspire Medical Systems) received FDA approval in May 2014. In 2011, Apnex Medical received FDA approval to conduct a randomized investigational device exemption (IDE) trial for the Hypoglossal Nerve Stimulation (HGNS®) System. The trial was terminated and Apnex Medical has ceased operations.

In 2014, ImThera™ Medical received FDA approval for an IDE trial with the aura6000® hypoglossal nerve stimulator system.

EVIDENCE SUMMARY

Continuous positive airway pressure (CPAP) is the most widely accepted medical therapy for treatment of obstructive sleep apnea (OSA) and improvement of primary health outcomes such as cardiovascular disease, type 2 diabetes, and overall mortality associated with OSA.^[5] Surgical interventions are being proposed as a second line treatment for, patients who have failed CPAP.

Large well-designed, 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 mandibular-maxillary advancement (MMA), and hypoglossal nerve stimulation 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 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.^[5,6]
- 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.^[7]
- 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.^[7]
- Hypoglossal nerve stimulation is similar to UPPP and hyoid suspension procedures, in that no randomized controlled trials have been identified. Evidence from nonrandomized comparative studies and prospective single-arm studies demonstrate clinically meaningful improvements in patients with moderate-to-severe sleep apnea who failed conservative treatment and had a favorable pattern of palatal collapse. The medical community has adopted hypoglossal nerve stimulation into practice for this select population.

Evidence is uncertain for use of any other surgical interventions in the treatment of OSA, including but not limited to uvulectomy, tongue base reduction and minimally invasive surgical

procedures such as laser-assisted uvuloplasty (LAUP), radiofrequency tongue base reduction (RFTBR), hypoglossal nerve stimulation, 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 concluded with this statement: “Overall, the strength of evidence is insufficient to evaluate the relative efficacy of surgical interventions for the treatment of OSA.”^[5] 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.^[6,8] 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.^[9] 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).^[10-13] 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.^[12] The relevant trials are described in greater detail next.

RADIOFREQUENCY VOLUMETRIC TISSUE REDUCTION OF THE TONGUE BASE OR PALATAL TISSUES

Systematic Reviews

Baba performed a systematic review and meta-analysis that addressed the efficacy of temperature controlled radiofrequency tissue ablation (TCRFTA) to alleviate symptoms of OSA.^[14] 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 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 TCRFTA 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, published a meta-analysis of RFA for the treatment of OSA in patients with a RDI of 5 or more.^[15] 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 (eg, 50% reduction in RDI) was not reported. This meta-analysis is limited by the inclusion of poor quality uncontrolled studies.

Randomized Controlled Trials

A single-blinded RCT of single-stage radiofrequency surgery of the soft palate was reported in 2009.^[16] 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 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.

An RCT from 2009 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 ≥ 15).^[17] Patients with a BMI of 35 kg/m² 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/mg².

A 2003 study by Woodson compared the use of multilevel RFA with the current criterion standard of continuous positive airway pressure (CPAP) in an RCT.^[11] The study included patients with mild obesity levels (BMI ≥ 34 kg/m²) 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.^[18] 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.^[19] This subgroup likely contains overlapping patients with the previous report, and the results were similar (ie, 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.^[20] 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 3-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 (SaO₂); 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 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.^[21,22] 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.

TONGUE BASE SUSPENSION PROCEDURES

Systematic Review

In 2013, Handler reported a systematic review of tongue suspension versus hypopharyngeal surgery for the treatment of OSA.^[23] 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 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 ≥ 15).^[17] 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/mg². 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.^[24] 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.^[25] 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.^[26] 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.^[27] 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.^[28-30]

LASER-ASSISTED PALATOPLASTY (LAUP)

Randomized Controlled Trials

Ferguson reported on 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.^[10] 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.^[31] 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

There is limited evidence regarding cauterly-assisted palatal stiffening operation (CAPSO) in patients with clinically significant OSA; most studies on CAPSO focus on patients with simple snoring (AHI <5) or mild sleep apnea (AHI <15).^[32,33] In 2000, Wassmuth reported a case series of 25 patients with OSA who underwent CAPSO.^[34] Responders were defined as patients who had a reduction in AHI of at least 50%. Mean AHI improved from 25.1±12.9 to 16.6±15.0. The broad confidence intervals limit interpretation of these data.

PALATAL IMPLANTS

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.^[35] 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.^[36] Patients with BMI greater than 32 kg/m² were excluded from the study. About 1000 patients were evaluated to identify the 100 study patients. At 3-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.^[37] Other inclusion criteria included: Friedman tongue position I, II, or III; diagnosis of mild to moderate OSA (AHI ≥ 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/m². 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 3-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.^[38] This study included 92 patients with mild to moderate OSA (AHI ≤ 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.^[39,40] 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 8 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 3- to 7-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.^[41] 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 1 year, whereas 13 patients (50 %) had a 50 % or greater reduction to an AHI less than 10 at 1 year. Mean AHI was reduced from 16.5 +/- 4.5 at baseline to 12.5 +/- 10.5 at 3 months ($p < 0.014$) and to 12.3 +/- 12.7 at 1 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 ≤ 30 .^[42] 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 ≤ 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).^[43] 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.^[44,45] 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 study is 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.

IMPLANTABLE HYPOGLOSSAL NERVE STIMULATORS

Systematic Reviews

A 2015 systematic review identified six case series with a total of 200 patients treated with hypoglossal nerve stimulation.^[46] No controlled trials were identified. Two series were identified on the Inspire II System and included the STAR trial described below. Three series were identified with the HGNS system and included the study of 31 patients described above. One series of 13 patients was identified with the aura6000 System (ImThera Medical). When data were combined for meta-analysis, AHI and Oxygen Desaturation Index (ODI) improved by 50% (eg, AHI from 44 to 20, ODI from 21 to 10), and the ESS improved from 12 to 7. All of the included studies described minor complications such as tongue weakness, tongue soreness, pain/swelling at the neck incision, fever, and lack of tongue response to stimulation. Of the 200 patients, nine (4.5%) had serious device-related adverse events that led to removal of the stimulator.

Nonrandomized Studies

The largest nonrandomized study published to date is an industry-sponsored prospective multicenter, single-arm study (n=126) of the Inspire® Upper Airway Stimulation system. The reports published on this cohort are described below.

In 2018, Woodson reported 5-year outcomes from the STAR trial (N=97).^[47] Seventy-one participants agreed to a PSG. AHI success was reported in 63 percent of patients (mean score of 12.4 [SD 16.3]). Oxygen Desaturation Index, Functional Outcomes of Sleep Questionnaire, and Epworth Sleepiness Scale scores showed the 12-month results were maintained. Device-related adverse events were also reported (percent of participants of 126) and included discomfort due to electrical stimulation (60.3), tongue abrasion (27), dry mouth (15.1), mechanical pain from device (11.1), and internal (16.7) and external (26.2) device usability.

Gillespie reported on outcomes after 48 months of follow-up in the STAR trial in 2017.^[48] Ninety-one patients completed the 48-month visit. Epworth Sleepiness Scale (ESS), Functional Outcomes of Sleep Questionnaire (FOSQ), and snoring level, were compared with baseline; daytime sleepiness was significantly reduced, and sleep-related quality of life significantly improved.

In 2015, the STAR Trial Group reported 36-month outcomes from the STAR trial, described below.^[49] Of 126 enrolled participants, 116 (92%) completed 36-month follow-up evaluation; 98 of these also underwent a 36-month polysomnography (PSG). In the PSG group, 74% had a reduction of AHI from the median value of 28.2 events per hour at baseline to 8.7 and 6.2 at 12 and 36 months, respectively. At 36 months snoring, as reported by partner decreased, and

self-reported outcomes that had improved from baseline to 12 months were maintained at 36 months.

In 2014, the STAR Trial Group reported 12-month outcomes from a multicenter, single-arm study (n=126) of the Inspire® Upper Airway Stimulation system.^[50] Patients were included if the AHI score from the screening PSG was between 20 to 50 events per hour. At 12 months after implantation 66% of patients had at least a 50% decrease in AHI with a final AHI of less than 20 events per hour, and 75% of patients had a reduction in the oxygen desaturation index score of 25% or more. The median AHI decreased from 29.3 to 9.0 events per hour (mean, 32.0-15.3) and the oxygen desaturation index score (number of times per hour that SO₂ drops by 4%) decreased from 25.4 to 7.4 events per hour (mean, 29.9-13.9). The mean ESS decreased from 11.6 to 7.0. The first 46 patients who responded to therapy were then randomized to either continued therapy or withdrawal from therapy.^[51] After seven days, AHI of the continued treatment group remained stable from a mean of 7.2 to 8.9 events per hour, whereas the mean AHI in the withdrawal group increased from 7.6 to 25.8. Eighteen percent of participants had temporary tongue weakness and 21% reported tongue soreness, including abrasion, which resulted from stimulation-induced tongue motion over the lower teeth. At 18 month follow-up, AHI and ODI scores had returned to levels observed at 12 months.^[52]

PRACTICE GUIDELINE SUMMARY

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.^[4,53-58] 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, UPPP, 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 mandibular-maxillary 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.

Evidence for hypoglossal nerve stimulation (HNS) as a treatment of obstructive sleep apnea (OSA) or airway resistance syndrome (UARS) is limited. However, HNS has become generally accepted in medical practice. Therefore, hypoglossal nerve stimulation may be considered medically necessary for some patients with OSA or UARS when policy criteria

are met. The use of hypoglossal nerve stimulation is considered investigational for the treatment of OSA or UARS when policy criteria are not 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 CPAP. In addition, surgical treatments including uvulopalatopharyngoplasty (UPPP) and its variants, hyoid suspension, mandible osteotomy, partial glossectomy, and maxillofacial surgeries such as mandibular-maxillary 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, tongue base reduction, and minimally invasive surgical procedures such as laser-assisted uvuloplasty (LAUP), radiofrequency tongue base or tissue volume reduction, pillar stiffening procedures and pillar implants. The use of these interventions is 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
	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
	41500	Fixation of tongue, mechanical, other than suture (eg, K-wire) (Deleted 1/1/2019)
	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

Codes	Number	Description
	64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
	0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)
	0467T	Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator
	0468T	Removal of chest wall respiratory sensor electrode or electrode array
HCPCS	S2080	Laser-assisted uvulopalatoplasty (LAUP)

Appendix 1: Procedures for the Diagnosis of Sleep Disordered Breathing	
Polysomnography (PSG)	<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>
Split Night Polysomnography	<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>
Ambulatory or Portable Home Monitoring Device (PM)	<p>A variety of portable polysomnography monitors are available for use in the home setting. Available devices evaluate different parameters including oximetry, respiratory and cardiac monitoring, and sleep/wake activity, but the majority of portable monitors do not record EEG. While evidence indicates that portable monitoring can be a safe and effective method to evaluate OSA, there is a lack of standardization among devices and</p>

Appendix 1: Procedures for the Diagnosis of Sleep Disordered Breathing	
	<p>additional study is needed to determine the most reliable types of devices and combinations of home monitoring.</p> <p>The following information may be useful in determining whether to use a portable home monitoring device:^[53,60]</p> <ul style="list-style-type: none"> • Portable monitoring should only be conducted in patients with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation. • A positive portable study with at least 3 channels of recording (e.g., arterial oxygen saturation, airflow, respiratory effort, or heart rate) has a high positive predictive value for OSA and can be used as the basis for a CPAP trial to determine efficacy of treatment. • A negative study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or who do not respond to CPAP should undergo further evaluation. • Due to the probability of artifacts or loss of data, raw data from the portable monitoring device should be reviewed by a sleep specialist. <p>Follow-up and review of the APAP trial is also needed.</p>
SNAP™ Testing	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.
Multiple Sleep Latency Tests (MSLT)	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. MSLT is used in patients with complaints of irresistible daytime sleepiness suggestive of narcolepsy.
Maintenance of Wakefulness Test (MWT)	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.
Radiologic Studies	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.
Endoscopic Studies	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.
Epworth Sleepiness Scale	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

Appendix 1: Procedures for the Diagnosis of Sleep Disordered Breathing	
	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.
Apnea-Hypopnea Index (AHI); Respiratory Disturbance Index (RDI)	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.
Polysomnography (PSG)	<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>
Split Night Polysomnography	<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>

Appendix 2: Nonsurgical Devices for Treatment of OSA or UARS	
CPAP	Nasal or oral continuous positive airway pressure (CPAP) or auto-titrating continuous positive airway pressure (APAP) is continuous positive airway

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	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.
BiPAP®	<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>
APAP	<p>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.</p>
Oral Appliances (OA)	<p>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 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.^[61,62] 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®).</p>

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