Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Description

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This policy addresses the various surgical procedures that have been evaluated for the treatment of adult and pediatric patients with OSA.

Background

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. In patients with OSA, the normal pharyngeal narrowing may be accentuated by anatomic factors, such as a short, fat “bull” neck, elongated palate and uvula, and large tonsillar pillars with redundant lateral pharyngeal wall mucosa. In addition, OSA is associated with obesity. OSA may also be associated with a variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. Obstruction anywhere along the upper airway can result in apnea. Therefore, OSA is associated with a heterogeneous group of anatomic variants producing obstruction.

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 lead to impairment of daytime activity. For example, adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, i.e., cars, trucks, or 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 also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.
Diagnosis: The final diagnosis of OSA rests on a combination of clinical evaluation and objective criteria to identify those levels of obstruction that are considered to be clinically significant (see policy No. 2.01.18). The gold standard diagnostic test for sleep disorders is considered a polysomnogram, which includes sleep staging to assess arousals from sleep, and determination of the frequency of apneas and hypopneas from channels measuring oxygen desaturation, respiratory airflow, and respiratory effort. An obstructive apnea is defined as at least a 10-second drop in respiration (at least 90% drop of peak signal excursion) associated with ongoing ventilatory effort. Obstructive hypopnea is a 30% or greater reduction of air exchange with an associated fall in oxygen saturation of at least 34%. Respiratory event-related arousals (RERAs) are scored if there is a sequence of breaths lasting at least 10 seconds characterized by increasing respiratory effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea or hypopnea. The apnea/hypopnea index (AHI) is defined as the total number of apneas and hypopneas per hour of sleep. The respiratory disturbance index (RDI) may be defined as the number of apneas, hypopneas, and RERAs per hour of sleep. When sleep onset and offset are unknown (e.g., in home sleep studies), the RDI may be calculated based on the number of apneas and hypopneas per hour of recording time. OSA is considered to be clinically significant when an adult patient has an AHI greater than 5 and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI greater than or equal to 15 is typically considered moderate OSA, while an AHI greater than 50 is considered severe OSA. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds. Hypopneas are scored by a 50% or greater drop in nasal pressure and either an equal to or greater than 3% decrease in oxygen saturation or an associated arousal. In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 or more is considered severe.

A condition related to OSA has been termed upper airway resistance syndrome (UARS). UARS is characterized by a partial collapse of the airway resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha electrocardiogram (EEG) arousals (RERAs). UARS can occur in the absence of snoring and in patients who are not overweight. The resistance to airflow is typically subtle and does not result in apneic or hypopneic events. However, increasingly negative intrathoracic pressure during inspiration can be measured using an esophageal manometer. 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. In the absence of intrathoracic pressure monitoring, a positive response to continuous positive airway pressure (CPAP) has also been used to support the diagnosis.

Treatment: Nonsurgical treatment for OSA or UARS includes CPAP or orthodontic repositioning devices, which are addressed in policy No. 2.01.18. Traditional surgeries for OSA or UARS include uvulopalatopharyngoplasty (UPPP) and a variety of maxillofacial surgeries such as mandibular-maxillary advancement (MMA). UPPP involves surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. The amount of tissue removed is individualized for each patient as determined by the potential space and width of the tonsillar pillar mucosa between the 2 palatal arches. The UPPP enlarges the oropharynx but cannot correct obstructions in the hypopharynx. Thus, patients who fail UPPP may be candidates for additional
procedures, depending on the site of obstruction. Additional procedures include hyoid suspensions, maxillary and mandibular osteotomies, or modification of the tongue. Fiberoptic endoscopy and/or cephalometric measurements have been used as methods to identify hypopharyngeal obstruction in these patients. The first-line treatment in children is usually adenotonsillectomy. Minimally invasive surgical approaches being evaluated for OSA in adults include the following:

*Laser-assisted Uvulopalatoplasty (LAUP):* LAUP is an outpatient alternative that has been proposed as a treatment of snoring with or without associated OSA. In this procedure, superficial palatal tissues are sequentially reshaped using a carbon dioxide 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. One purported advantage of LAUP is that the amount of tissue ablated can be titrated such that the treatment can be discontinued once snoring is eliminated. 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, which raises its own issues of safety and, in particular, effectiveness.

*Radiofrequency Ablation (RFA) of Palatal Tissues and the Tongue:* RFA of the soft palate is similar in concept to LAUP, although a different energy source is used. Radiofrequency is used to produce thermal lesions within the tissues rather than using a laser to ablate the tissue surface, which may be painful. For this reason, RFA appears to be growing in popularity as an alternative to LAUP. In some situations, radiofrequency of the soft palate and base of tongue are performed together as a multilevel procedure.

*Tongue Base Suspension:* In this procedure, the base of the tongue is suspended with a suture that is passed through the tongue and then fixated with a screw to the inner side of the mandible, below the tooth roots. The aim of the suspension is to make it less likely for the base of the tongue to prolapse during sleep.

*Palatal Stiffening:* Palatal stiffening procedures include insertion of palatal implants, injection of a sclerosing agent (snoreplasty), or a cautery-assisted palatal stiffening operation (CAPSO). The CAPSO procedure uses cautery to induce a midline palatal scar designed to stiffen the soft palate to eliminate excessive snoring. The palatal implant device is a cylindrical-shaped segment of braided polyester filaments that is permanently implanted submucosally in the soft palate.

**Regulatory Status**

The Somnoplasty® device has been cleared for marketing by the U.S. Food and Drug Administration (FDA) for radiofrequency ablation of palatal tissues for simple snoring and for the base of the tongue for OSA.

The Repose™ Bone Screw System (Influence, San Francisco, CA) was cleared for marketing through the 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 pre-threaded suture. It is indicated for the treatment of OSA and/or snoring.
The Pillar™ Palatal Implant System (Restore Medical, St. Paul, 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).”

Related Policies

2.01.18 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Uvulopalatopharyngoplasty (UPPP) may be considered medically necessary for the treatment of clinically significant obstructive sleep apnea syndrome (OSA) in appropriately selected adult patients who have not responded to or do not tolerate nasal continuous positive airway pressure (CPAP). Clinically significant OSA is defined as those patients who have:

- Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered medically necessary in appropriately selected adult patients with clinically significant OSA and objective documentation of hypopharyngeal obstruction who have not responded to or do not tolerate CPAP. Clinically significant OSA is defined as those patients who have:

- AHI or RDI greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

Adenotonsillectomy may be considered medically necessary in pediatric patients with clinically significant OSA and hypertrophic tonsils. Clinically significant OSA is defined as those pediatric patients who have:

- AHI or RDI of at least 5 per hour, or
- AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity.

The following minimally-invasive surgical procedures are considered investigational for the sole or adjunctive treatment of obstructive sleep apnea (OSA) or upper airway resistance syndrome (UARS):

- Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues
- Laser-assisted palatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants
- Tongue base suspension
- All other minimally-invasive surgical procedures not described above.

All interventions, including LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, are considered **not medically necessary** for the treatment of snoring in the absence of documented OSA; snoring alone is not considered a medical condition.

**Policy Guidelines**

Clinically significant obstructive sleep apnea (OSA) is defined as those adult patients who have:
- Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

The AHI is the total number events (apnea or hypopnea) per hour of recorded sleep. The RDI is the total number events (apnea or hypopnea) per hour of recording time. An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

The presentation of OSA in pediatric patients may differ from that of adults. OSA in pediatric patients is defined as those who have:
- AHI or RDI of at least 5 per hour, or
- AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity.

Clinically significant upper airway resistance syndrome (UARS) is defined as greater than 10 EEG arousals per hour. The presence of abnormally negative intrathoracic pressures (i.e., more negative than 10 cm) in conjunction with the EEG arousals supports the diagnosis. The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram. Objective evidence of hypopharyngeal obstruction is documented by either fiberoptic endoscopy or cephalometric radiographs.
Rationale

This policy was originally based on TEC Assessments on the surgical management and radiofrequency volumetric tissue reduction of obstructive sleep apnea (OSA) and updated with periodic literature searches. (1, 2) The most recent update was performed through April 17, 2013.

Literature Review

In 2011, the Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review (CER) on the diagnosis and treatment of OSA in adults. (3) The available evidence was considered insufficient to evaluate the efficacy of surgical interventions for the treatment of OSA.

A 2009 systematic review by Franklin and colleagues evaluated benefits and adverse effects of surgery for snoring and OSA. (4) 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 side effects, especially difficulty swallowing.
- Four RCTs, rated as high quality, were identified for laser-assisted palatoplasty (LAUP) and radiofrequency ablation (RFA). (5-8) 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. (6) The relevant trials are described in greater detail below.

Maxillomadibular Advancement (MMA)

An RCT that compared MMA to conservative management with ventilation was reported in 2010. (9) Fifty patients with AHI greater than 30 were randomized to MMA or autotitrating positive airway pressure (APAP); there were no exclusions for body mass index (BMI). Blinding was not considered possible due to the types of treatment. No differences in outcomes were found between the groups. At baseline, AHI was 57 in the MMA group and 50 in the APAP group. At 1-year follow-up, AHI had decreased to 8 following surgery and 6 with use of APAP. The Epworth Sleepiness Scale (ESS) decreased from 11.6 to 7.7 with MMA and from 11.2 to 5.9 with APAP. Three patients were not able to tolerate APAP and crossed over to MMA (analysis of crossovers not clear), 4 required more than 3 consultations, and 3 required a different mask. In the surgery group, 7 patients reported a persistent but not disturbing paresthesia around the chin and 6 reported slight to minimal malocclusion. Satisfaction with surgery was reported to be high (88% of patients reported satisfaction ≥90 out of 100, compared with 56% for APAP).
Adenotonsillectomy

Three systematic reviews were published in 2009 on tonsillectomy for obstructive sleep apnea in children. (10-12) Kuhle and colleagues reviewed randomized trials on interventions for children with OSA. (10-11) The single RCT on surgical interventions that was identified compared RFA of the tonsils with conventional adenotonsillectomy. Both procedures were found to reduce the respiratory disturbance index (RDI) (from 7.7 and 7.6/h to 0.3 and 1.6/h, respectively). Friedman et al. performed a meta-analysis of 23 studies (1,079 children with a mean age of 6.5 years) to evaluate success rates of tonsillectomy and adenoidectomy for pediatric OSA. (11) The mean preoperative AHI was 18.6 and the mean postoperative AHI was 4.9, with a mean change after surgery of 12.4 events per hour. Although limited by heterogeneity, the success rate was found to be 66% when success was defined as an AHI less than 5 and 60% when success was defined as an AHI less than 1. Further analysis found that the success rate (AHI <5) was only 39% in children with co-morbidities such as obesity compared to a 74% success rate observed in uncomplicated patients. Due to likely publication bias, the authors concluded that these rates should be considered an upper limit of success. Costa and Mitchell also reported lower efficacy in obese children from their meta-analysis of 4 studies reporting on this population. (12) The mean pre- and postoperative AHI was 29.4 and 10.3, respectively. Following adenotonsillectomy, 49% of obese children had a postoperative AHI less than 5, 25% had a postoperative AHI less than 2, and 12% had a postoperative AHI less than 1.

Laser-Assisted Uvulopalatoplasty (LAUP)

Ferguson and colleagues reported on a trial that randomized 45 subjects with mild to moderate sleep apnea (defined as an AHI ranging between 10 and 27 per hour) to either LAUP or no treatment. (5) 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.

Radiofrequency Volumetric Reduction of Palatal Tissues and Base of Tongue

The policy on radiofrequency volumetric tissue reduction (i.e., Somnoplasty®) was originally based on a 2000 TEC Assessment of 4 primary studies on palatal RFA and 1 study on tongue base RFA. (2) All studies were nonrandomized and enrolled preselected patients. The Assessment concluded that data were inadequate to make a conclusion at that time.

In 2008, Farrar and colleagues published a meta-analysis of RFA for the treatment of OSA in patients with a RDI of 5 or more. (13) Sixteen studies met the inclusion criteria; 3 were randomized and 13 were nonrandomized. Six studies treated both the base of the tongue and the soft palate, 2 treated the soft palate only, and 8 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 6 of the studies, the average baseline Epworth Sleepiness Scale (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 of 3 to 7). Complications were noted in 4% of patients; 2 tongue abscesses progressed to airway obstruction requiring tracheotomy. Only 2 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. Higher quality studies are described below.

A single-blinded RCT of single-stage radiofrequency surgery of the soft palate was reported in 2009. (14) 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 post-treatment (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 4 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 side effects of 2 tongue-based procedures (RFA or tongue-base suspension) when combined with UPPP in patients with moderate to severe sleep apnea (AHI >15). (15) 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, success rates for the combined procedures (defined as an >50% reduction and final AHI <15) were 51% to 57%, respectively. BMI was the main predictor of success, with success rates of only 10% to 12.5% in patients with a BMI between 30 and <35 kg/m2. Morbidity was higher with the tongue suspension procedure.

A 2008 retrospective cohort study assessed the incremental value of RFA of the tongue in combination with UPPP. (16) 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, gender, BMI, AHI, and mean 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 authors concluded that the addition of RFA to UPPP resulted in only limited improvement, but there was no major downside to it.

A 2003 study by Woodson and colleagues compared the use of multilevel RFA with the current gold standard of continuous positive airway pressure (CPAP) in an RCT. (6) The study included patients with mild obesity levels (BMI of 34 or greater) 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. (17) Specifically, the authors focused on multi-level treatments on various combinations of palatal and tongue tissues. The authors reported that greater improvements in quality of life were reported for those patients who had a total of 5 treatments compared to 3. Another subgroup analysis focused on multi-level treatments in 26 patients. (18) 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 5 treatments.

**Palatal Stiffening Procedures**

*Cautery-Assisted Palatal Stiffening Operation (CAPSO)*

There is limited evidence regarding 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). (19, 20) In 2000, Wassmuth and colleagues reported a case series of 25 patients with OSA who underwent CAPSO. (21) 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*

In a 2008 trial by Steward et al., 100 patients with mild to moderate OSA and suspected retropalatal obstruction were randomly assigned to palatal implants or sham placebo. (22) Patients with BMI greater than 32 kg/m2 were excluded from the study. About 1,000 patients were evaluated to identify the 100 study patients. At 3 months’ 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 2 patients (4%).

Friedman et al. reported an industry-sponsored randomized double-blind, sham-controlled trial of palatal implants in 62 patients with symptoms of OSA. (23) Other inclusion criteria included: Friedman tongue position I, II, or III; diagnosis of mild to moderate OSA (AHI >5 and <40) on baseline PSG; a soft palate of 2 cm or more but less than 3.5 cm; and body mass index (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 intent-to-treat (ITT) 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 (from 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.

In 2012, Maurer and colleagues reported a randomized, double-blind, sham-controlled trial of the Pillar palatal implant in 20 patients with mild to moderate OSA due to palatal obstruction. (24) 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.

There are also uncontrolled series of patients treated with palatal implants. For example, Walker and colleagues published 90-day and 15-month follow-up from a multicenter study on palatal implants (Pillar System) in 63 subjects. (25, 26) 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 9 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 analogue scale [VAS]), and 4 at both 90 days and 15 months. Subjective daytime sleepiness measured by the ESS was reduced at 90 days (from 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.

Neruntarat reported a case series with a minimum of 24-month follow-up. (27) 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 7 patients (7.6%), and palatal abscess occurred in 1 patient (1.1%).

Conclusions: The literature on palatal implants consists of 3 randomized controlled trials 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 to 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.

Practice Guidelines and Position Statements

In 2001, the American Academy of Sleep Medicine (AASM) published practice parameters for the use of laser-assisted uvulopalatoplasty, stating that LAUP is not recommended for treatment of OSA. (28) This position (Guideline) was restated in AASM clinical guidelines for the evaluation, management, and long-term care of OSA in adults, published in 2009. (29) All other recommendations in the 2009 clinical guidelines for surgical treatment of OSA were consensus-based.

The AASM published practice parameters for surgical modifications of the upper airway for OSA in 2010. (30) The AASM practice parameters were based on a systematic review of the evidence that found that the published literature was comprised primarily of case series, with few controlled trials and varying approaches to pre-operative evaluation and postoperative follow-up. (31) Using the
change in AHI as the primary measure of efficacy, substantial and consistent reductions were observed following MMA, and adverse events were uncommonly reported. Outcomes following pharyngeal surgeries were less consistent, and adverse events were more commonly reported. The review found that outcomes of studies with newer pharyngeal techniques and multi-level procedures, performed in small numbers of patients, appear promising. The practice parameters noted the lack of rigorous data evaluating surgical modifications of the upper airway, resulting in a recommendation of “option” (uncertain clinical use) for MMA, UPPP as a sole procedure, or multi-level or stepwise surgery if patients failed UPPP as a sole treatment. Use of RFA received a recommendation of “option” for patients with mild to moderate OSA who cannot tolerate or who are unwilling to adhere to CPAP, or in whom oral appliances have been found ineffective or undesirable. Palatal implants received a recommendation of “option” for patients with mild OSA who failed medical therapy. LAUP is not recommended as a routine treatment for OSA (standard). The practice parameters committee gave a recommendation of “standard” for the determination of the presence and severity of OSA before initiating surgical therapy, discussion of success rates, complications, and alternative treatments with the patient, and a postoperative follow-up evaluation, which includes a clinical evaluation and an objective measure of the presence and severity of sleep-disordered breathing and oxygen saturation. However, little guidance was available in the medical literature to recommend any particular monitoring strategy. The optimal interval and duration of this follow-up are also not clear from the available literature.

In 2011, the American Academy of Otolaryngology – Head and Neck Surgery published clinical practice guidelines on polysomnography (PSG) for sleep-disordered breathing prior to tonsillectomy in children. (32) In addition to recommendations for PSG (see policy No. 2.01.18), the committee made the following recommendation: clinicians should admit children with OSA documented on PSG for inpatient, overnight monitoring after tonsillectomy if they are younger than age 3 years or have severe OSA (AHI of >10, oxygen saturation nadir <80% or both).

The American Academy of Pediatrics (AAP) published a 2002 guideline on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting; complex high-risk patients should be referred to a specialist. (33) Adenotonsillectomy is the first line of treatment for most children, and CPAP is an option for those who are not candidates for surgery or do not respond to surgery; patients should be reevaluated postoperatively to determine whether additional treatment is required. No updates of this guideline have been identified.

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) has a policy statement, most recently updated in 1998, on surgical management of OSA. (34) 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 tracheotomy, nasal and pharyngeal airway surgery, UPPP; UPP (including laser assisted and other techniques), genioglossal advancement, hyoid repositioning, midline glossectomy, lingualplasty, and maxillary and mandibular advancement. While this organization previously noted further studies were needed to document the effects of LAUP, it did not provide citations of any studies supporting its rationale for the amended statement.
Summary

There is a great range of severity of OSA, with symptoms ranging from snoring only to severe excessive daytime sleepiness or hypertension. If OSA is considered mild (AHI between 5 and 15) and snoring is the only manifestation, intervention is considered not medically necessary.

Adenotonsillectomy may be considered medically necessary in pediatric patients with OSA. Standard surgical procedures (i.e., UPPP and maxillofacial procedures) have been found to improve symptoms in adult patients with clinically significant OSA. Due to the likelihood of adverse effects, surgery should be limited to patients who are unable to tolerate CPAP. Minimally-invasive surgical procedures have limited efficacy in patients with mild to moderate OSA and have not been shown to improve AHI or excessive daytime sleepiness in adult patients with moderate to severe OSA. These are considered not medically necessary.

Medicare National Coverage

In 2001, the Centers for Medicare and Medicaid Services (CMS) published a decision memorandum for CPAP that addressed the issue of how to define moderate to severe OSA as a guide to a coverage policy for CPAP. Since surgical approaches are considered when CPAP fails, the Medicare policy has been adapted to this policy on surgical management of OSA. The Medicare review of the literature suggested that there is a risk of hypertension with an AHI greater than 15, and thus treatment is warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 and associated symptoms, the CMS document concluded that the data from 3 RCTs demonstrated improved daytime somnolence and functioning in those treated with CPAP.

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Surgical management of sleep apnea. TEC Assessments 1995; Volume 10, Tab 32.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Radiofrequency volumetric tissue reduction for sleep-related breathing disorders. TEC Assessments 2000; Volume 15, Tab 15.


Policy History

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<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>September 2013</td>
<td>Updated Policy</td>
<td>Policy updated with literature search. Background information significantly revised. References added. Policy summary revised with intent unchanged, policy statement unchanged.</td>
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Keywords

- Cautery-Assisted Palatal Stiffening Operation
- Laser-Assisted uvulopalatoplasty (LAUP)
- Mandibular-Maxillary Advancement (MMA)
- Obstructive Sleep Apnea Syndrome, Surgical Management
- Palatal Stiffening Procedure
- Pillar Palatal Implant System
- Radiofrequency Ablation of Palatal Tissue
- Sleep Apnea Syndrome, Surgical Management
- Snoring, Minimally Invasive Surgery
- Somnoplasty
- Surgical Management of Obstructive Sleep Apnea Syndrome, Minimally Invasive
- Upper Airway Resistance Syndrome
- Uvulopalatopharyngoplasty (UPPP)

This policy was approved by the FEP Pharmacy and Medical Policy Committee on September 20, 2013 and is effective November 1, 2013.

Signature on file

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