



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

**Policy #** 00329

Original Effective Date: 07/27/2012  
Current Effective Date: 07/16/2014

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome is addressed separately in medical policy 00328.*

*Note: Actigraphy is addressed separately in medical policy 00330.*

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

### Uvulopalatopharyngoplasty

Based on review of available data, the Company may consider uvulopalatopharyngoplasty (UPPP) for the treatment of clinically significant obstructive sleep apnea syndrome (OSA) in appropriately selected adult patients who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA) to be **eligible for coverage**.

### *Patient Selection Criteria*

Coverage eligibility will be considered for uvulopalatopharyngoplasty (UPPP) for the treatment of clinically significant obstructive sleep apnea syndrome (OSA) in appropriately selected adult patients who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA). Clinically significant obstructive sleep apnea syndrome (OSA) is defined as those patients who meet the following criteria:

- Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour; or
- Apnea/hypopnea index (AHI) or respiratory disturbance index (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

Based on review of available data, the Company may consider hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), in appropriately selected adult patients with clinically significant obstructive sleep apnea syndrome (OSA) and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA) to be **eligible for coverage**.

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### *Patient Selection Criteria*

Coverage eligibility will be considered for hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), in appropriately selected adult patients with clinically significant obstructive sleep apnea syndrome (OSA) and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA). Clinically significant obstructive sleep apnea syndrome (OSA) is defined as those patients who meet the following criteria:

- Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour; or
- Apnea/hypopnea index (AHI) or respiratory disturbance index (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

Based on review of available data, the Company may consider adenotonsillectomy in pediatric patients with clinically significant obstructive sleep apnea syndrome (OSA) and hypertrophic tonsils to be **eligible for coverage**.

### *Patient Selection Criteria*

Coverage eligibility will be considered for adenotonsillectomy in pediatric patients with clinically significant obstructive sleep apnea syndrome (OSA) and hypertrophic tonsils. Clinically significant obstructive sleep apnea syndrome (OSA) is defined as those patients who meet the following criteria:

- Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) of at least 5 per hour; or
- Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity.

### **When Services Are Considered Not Medically Necessary**

Based on review on available data, the Company considers surgical treatment of obstructive sleep apnea syndrome (OSA) that does not meet the criteria above to be **not medically necessary**.

Based on review on available data, the Company considers all interventions, including laser-assisted palatoplasty (LAUP), radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures for the treatment of snoring when criteria have not been met or in the absence of documented obstructive sleep apnea syndrome (OSA) to be **not medically necessary\*\***; snoring alone is not considered a medical condition.



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### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the following minimally-invasive surgical procedures for the sole or adjunctive treatment of obstructive sleep apnea syndrome (OSA) or upper Airway resistance syndrome (UARS) to be **investigational**\*:

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

Based on review of available data, the Company considers implantable hypoglossal nerve stimulators for all indications, including but not limited to the treatment of obstructive sleep apnea syndrome (OSA) to be **investigational**\*:

#### **Notes:**

*Continuous positive airway pressure (CPAP) is the preferred first-line treatment for most patients. A smaller number of patients may use oral appliances (OAs) as a first line treatment.*

*The AHI is the total number events (apnea or hypopnea) per hour of recorded sleep. The respiratory disturbance index (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 with baseline, and with at least a 4% oxygen desaturation.*

### **Background/Overview**

Obstructive sleep apnea 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 syndrome.

Obstructive sleep apnea syndrome 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. Obstructive sleep apnea may also be associated with a variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. Obstruction anywhere along



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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, ie, cars, trucks, heavy equipment. Obstructive sleep apnea 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. The criterion 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 ventilation (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 (SaO<sub>2</sub>) of at least 3% to %. 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 AHI is defined as the total number of apneas and hypopneas per hour of sleep. The RDI may be defined as the number of apneas, hypopneas, and RERAs per hour of sleep. When sleep onset and offset are unknown (eg, in home sleep studies), the RDI may be calculated based on the number of apneas and hypopneas per hour of recording time. Obstructive sleep apnea is considered to be clinically significant when an adult patient has an AHI of 5 or more and symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke. An AHI of 15 to 30 is typically considered moderate OSA, while an AHI of 30 or more 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 a 3% or more decrease in SaO<sub>2</sub> 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 UARS. Upper airway resistance syndrome is characterized by a partial collapse of the airway resulting in increased resistance to airflow. The increased respiratory effort

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is associated with multiple sleep fragmentations, as measured by very short alpha electrocardiogram (EEG) arousals RERAs. Upper airway resistance syndrome 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. Respiratory event-related arousals can also be detected absent manometry during polysomnography (PSG). 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. Traditional surgeries for OSA or UARS include UPPP and a variety of maxillofacial surgeries such as 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

Laser-assisted uvulopalatoplasty 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, because 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 of Palatal Tissues and the Tongue

Radiofrequency ablation (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.



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### 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.

### **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

The Somnoplast<sup>®‡</sup> device has been cleared for marketing by the FDA for RFA of palatal tissues for simple snoring and for the base of the tongue for OSA. FDA product code: GEI.

Airvance<sup>®‡</sup> (Medtronic; formally the Repose<sup>™‡</sup> Bone Screw System from Influence) 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 prethreaded suture. It is indicated for the treatment of OSA and/or snoring. The Encore<sup>™‡</sup> Tongue Suspension System (Siesta Medical) received clearance for marketing in 2011, citing the PRELUDE III Tongue Suspension System (Siesta Medical) as a predicate device. U.S. Food and Drug Administration product codes: LRK, ORY.

The Pillar<sup>®‡</sup> 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<sup>™‡</sup> 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)." U.S. Food and Drug Administration 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 trial for the Hypoglossal Nerve Stimulation (HGNS<sup>®‡</sup>) System.

### **Centers for Medicare and Medicaid Services (CMS)**

In 2001, the 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. Because 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



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concluded that the data from 3 RCTs demonstrated improved daytime somnolence and functioning in those treated with CPAP.

### **Rationale/Source**

#### **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. The available evidence was considered insufficient to evaluate the efficacy of surgical interventions for the treatment of OSA.

A 2009 systematic review by Franklin et al evaluated benefits and adverse effects of surgery for snoring and OSA. 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 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 LAUP and RFA. Study results were mixed and inconclusive for 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. The relevant trials are described in greater detail next.

#### **Maxillomandibular Advancement**

An RCT that compared MMA to conservative management with ventilation was reported in 2010. 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 of 100, compared with 56% for APAP).

#### **Adenotonsillectomy**

Three systematic reviews were published in 2009 on tonsillectomy for OSA in children. Kuhle et al reviewed randomized trials on interventions for children with OSA. The single RCT on surgical interventions that was identified compared RFA of the tonsils with conventional adenotonsillectomy. Both procedures were found to reduce the 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 (1079 children with a mean age of 6.5 years) to evaluate success rates of tonsillectomy and adenoidectomy for pediatric OSA. 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



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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 comorbidities such as obesity compared with a 74% success rate observed in uncomplicated patients. Because of 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. The mean pre- and postoperative AHI was 29.4 and 10.3, respectively. Following adenotonsillectomy, 49% of obese children had a postoperative AHI of less than 5, 25% had a postoperative AHI less than 2, and 12% had a postoperative AHI less than 1.

### Laser-Assisted Uvulopalatoplasty

Ferguson et al 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 LAUP or no treatment. 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.

### Tongue Suspension

In 2013, Handler et al reported a systematic review of tongue suspension versus hypopharyngeal surgery for the treatment of OSA. The review included 27 studies reporting on 4 separate procedures; tongue suspension alone, tongue suspension + UPPP, genioglossus advancement (GA) + UPPP, and GA + 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 (6 studies, 82 patients) had a success rate of 36.6%, while the success rate of tongue suspension + UPPP (8 studies, 167 patients) was 62.3%. A success rate of 61.1% was found for GA + UPPP (7 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).

One level II RCT included in the systematic review compared 2 tongue base surgeries (RFA or tongue-base suspension) combined with UPPP for moderate to severe sleep apnea (AHI >15). In the tongue suspension + 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 >50% reduction, final AHI <15, and ESS <11) was 57.1%, compared with a success rate of 51.7% in the UPPP + RFA group (p=0.79). Body mass index was the main predictor of success, with a success rate for tongue base suspension + UPPP of only 10% in patients with a BMI between 30 and <35 kg/m<sup>2</sup>. Morbidity and complications were higher with the tongue suspension procedure compared with RFA.



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### Radiofrequency Volumetric Reduction of Palatal Tissues and Base of Tongue

The policy on radiofrequency volumetric tissue reduction (ie, Somnoplasty) was originally based on a 2000 Technology Evaluation Centers (TEC) Assessment of 4 primary studies on palatal RFA and 1 study on tongue base RFA. 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 et al published a meta-analysis of RFA for the treatment of OSA in patients with a RDI of 5 or more. 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 ESS was less than 10. The meta-analysis indicated a 31% reduction in both ESS and RDI. The lowest SaO<sub>2</sub> 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; 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 (eg, 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 next.

A single-blinded RCT of single-stage radiofrequency surgery of the soft palate was reported in 2009. 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 57 patients with moderate-to -severe sleep apnea (AHI >15). Patients with a BMI of 35 kg/m<sup>2</sup> or greater were excluded. Although interpretation of results is limited by the lack of a control group treated with UPPP alone, the success rate for combined RFA + UPPP (defined as an >50% reduction and final AHI <15) was 51%. BMI was the main predictor of success, with success rates of only 12.5% in patients with a BMI between 30 and less than 35 kg/m<sup>2</sup>.

A 2008 retrospective cohort study assessed the incremental value of RFA of the tongue in combination with UPPP. 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 SaO<sub>2</sub>; however, no details were provided regarding the choice of procedure. With surgical success rate defined as more than 50% reduction of the AHI and AHI below 20, the success rate was 42% with UPPP alone and 49% with RFA (not significantly different). Two

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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.

A 2003 study by Woodson et al compared the use of multilevel RFA with the current criterion standard of CPAP in an RCT. The study included patients with mild obesity levels (BMI, 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. Specifically, the authors focused on multi-level 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 5 treatments compared with 3. Another subgroup analysis focused on multilevel treatments in 26 patients. 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 5 treatments.

### Palatal Stiffening Procedures

#### *Cautery-Assisted Palatal Stiffening Operation*

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). In 2000, Wassmuth et al reported a case series of 25 patients with OSA who underwent CAPSO. 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. Patients with BMI greater than 32 kg/m<sup>2</sup> were excluded from the study. About 1000 patients were evaluated to identify the 100 study patients. At 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. 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 BMI less than 32 kg/m<sup>2</sup>. AHI at baseline was 23.8 events per hour in the implant group and 20.1 in controls. Seven patients did not return for repeat PSG and were considered treatment failures in the 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 (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



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the successful treatment of 41.9% of implanted patients compared with 0% of controls. Two patients had partial implant extrusion.

In 2012, Maurer et al 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. At 90 days, the AHI in the treatment group improved from 19.1 to 8.2 events per hour and lowest SaO<sub>2</sub> 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 et al published 90-day and 15-month follow-up from a multicenter study on palatal implants (Pillar System) in 63 subjects. 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 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.

Neruntarat reported a case series with a minimum of 24-month follow-up. 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 SaO<sub>2</sub> was 87.4%. At mean 28.9-month follow-up, the AHI had decreased to 10.8, and the lowest SaO<sub>2</sub> 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%).

### Section Summary

The literature on palatal implants consists of 3 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 SaO<sub>2</sub> 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.

### Hypoglossal Nerve Stimulation

In 2014, the STAR Trial Group reported 12-month outcomes from a multicenter single-arm study (NCT01161420, n=126) of the Inspire<sup>®</sup> Upper Airway Stimulation system. Patients were included if the AHI score from the screening PSG was at least 20 and no more than 50 events per hour. At 12 months after implantation 66% of the participants met the coprimary outcome of at least a 50% decrease in AHI with a final AHI of less than 20 events per hour, and 75% met the coprimary outcome of a reduction in the oxygen



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desaturation index score of 25% or more. The median AHI decreased from 29.3 to 9.0 events per hour (mean, 32.0 to 15.3) and the oxygen desaturation index score (number of times per hour that SO<sub>2</sub> drops by 4% or more) decreased from 25.4 to 7.4 events per hour (mean, 29.9 to 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. After 7 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.

A series of 31 patients implanted with the Apnex hypoglossal nerve stimulation system (HGNS) was reported in 2014. The system is currently being studied in a Phase III randomized controlled trial (available at: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) NCT01446601). Both groups will undergo implantation of the HGNS system. The experimental group will have the system turned on at 1 month postimplant and the control arm will have the system turned on at 7 months postimplant. The study has an estimated enrollment of 132 patients with completion of data collection in 2013 and final study completion expected October 2017.

### 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 (ie, UPPP and maxillofacial procedures) have been found to improve symptoms in adult patients with clinically significant OSA. Because of 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 investigational. One system for hypoglossal nerve stimulation was recently approved by FDA. At this time, hypoglossal nerve stimulation has been studied in 2 series, the larger series had 12-month follow-up. Hypoglossal nerve stimulation for the treatment of OSA is considered investigational.

### Practice Guidelines and Position Statements

In 2001, the American Academy of Sleep Medicine (AASM) published practice parameters for the use of LAUP, stating that LAUP is not recommended for treatment of OSA. This position (Guideline) was restated in AASM clinical guidelines for the evaluation, management, and long-term care of OSA in adults, published in 2009. 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. 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 preoperative evaluation and postoperative follow-up. Using the change in AHI as the primary measure of efficacy, substantial and consistent reductions were observed following MMA, and adverse

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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 multilevel 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 multilevel 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 OAs 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 SaO<sub>2</sub>. 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.

The American Academy of Pediatrics (AAP) published a 2012 clinical practice guideline on the diagnosis and management of childhood OSA. AAP recommends that if a child has OSA, a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery, the clinician should recommend adenotonsillectomy as the first line of treatment. AAP recommends that patients should be referred for CPAP management if symptoms/signs or objective evidence of OAS persists after adenotonsillectomy or if adenotonsillectomy is not performed. Weight loss should be recommended in addition to other therapy if a child/adolescent with OSA is overweight or obese (Strength: Recommendation).

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) has a 2014 revised policy statement on surgical management of OSA. 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, tonsillectomy and adenoidectomy, palatal advancement, UPPP, UPP (including laser assisted and other techniques), genioglossal advancement, hyoid myotomy, midline glossectomy, tongue suspension, and maxillary and mandibular advancement. Links are provided to position statements on nasal surgery and OSA, midline glossectomy, tongue suspension, GA, hyoid myotomy, and UPPP. In the 2012 position statement on UPPP, AAO-HNS concluded that UPPP is a valid treatment of OSA. Either simultaneous or serial surgical procedures are considered medically necessary and effective for patients with mild to severe obstructive sleep apnea. A 2012 position statement recommends tongue suspension as effective when considered as part of a comprehensive approach in the medical and surgical management of adult patients with mild OSA and in adult patients with moderate and severe OSA who have evidence of tongue base or associated hypopharyngeal obstruction. The AAO-HNS notes that results appear to diminish in obese patients, and this technique should receive a weaker recommendation for these patients.



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In 2011, AAO-HNS published clinical practice guidelines on PSG for sleep-disordered breathing before tonsillectomy in children. In addition to recommendations for PSG, 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, SaO<sub>2</sub> nadir <80% or both).

In 2012, the American Society for Metabolic and Bariatric Surgery published guidelines on the perioperative management of OSA. The guideline states that OSA is strongly associated with obesity with the incidence of OSA in the morbidly obese population being reported to be between 38% and 88%. They recommend bariatric surgery be the initial treatment of choice for OSA in this population, as opposed to surgical procedures directed at the mandible or tissues of the palate.

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ICD-9 Diagnosis	327.20 thru 327.27, 780.50, 780.51, 780.53, 780.54, 780.57, 786.03, 786.04, 786.09, 786.1
ICD-9 Procedure	27.61 thru 27.69, 27.73, 29.4

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06/28/2012 Medical Policy Committee review  
07/27/2012 Medical Policy Implementation Committee approval. New policy.  
12/06/2012 Medical Policy Committee review  
12/19/2012 Medical Policy Implementation Committee. Coverage eligibility statement amended to clarify that the denial is not medically necessary when criteria are not met.  
06/27/2013 Medical Policy Committee review  
07/17/2013 Medical Policy Implementation Committee. No change to coverage.  
07/10/2014 Medical Policy Committee review  
07/16/2014 Medical Policy Implementation Committee approval. Changed the language throughout the "May Be Eligible for Coverage" section from "not responded to or do tolerate nasal continuous positive airway pressure (CPAP)" to "failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA)". Added that "surgical treatment of obstructive sleep apnea syndrome (OSA) that does not meet the criteria above" to the "Not Medically Necessary" section. Added investigational statement for hypoglossal nerve stimulation.

Next Scheduled Review Date: 07/2015

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