Name of Policy:
Surgical Treatment of Snoring and Obstructive Sleep Apnea

Policy #: 621                                      Latest Review Date: January 2017
Category: Surgical                                  Policy Grade: D

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. For patients who have failed conservative therapy, established surgical approaches may be indicated. This policy addresses the various surgical procedures that have been evaluated for the treatment of adult and pediatric patients with OSA.

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.

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, 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. 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 of at least 3% to 4%. 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 (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 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 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 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 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 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 065 Medical Management of Obstructive Sleep Apnea.

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**
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 from 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.

**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.

**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.

**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.

**Hypoglossal Nerve Stimulation**

Stimulation of the hypoglossal nerve results in contraction of the genioglossus muscle, the largest upper airway dilator muscle. This causes tongue protrusion and stiffening of the anterior pharyngeal wall, potentially leading to a decrease in apneic events. Hypoglossal nerve stimulation systems include an implantable neurostimulator, stimulating leads, and electrodes. Intermittent stimulation systems also include respiratory sensing leads. 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.

**Atrial Overdrive Pacing**

The use of atrial overdrive pacing (AOD) is also being evaluated in the treatment of obstructive sleep apnea. This approach is being tried because of the bradycardia that generally occurs during episodes of apnea.
Policy:

Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty (UPPP), uvulopharyngoplasty) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center or home study, (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.

Laser-assisted uvulopalatoplasty (LAUP) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center or home study, (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.

Laser-assisted uvulopalatoplasty (LAUP) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational when used for the treatment of snoring.

Genioglossal advancement, hyoid suspension and myotomy, and other mandibular-maxillary advancement meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of obstructive sleep apnea when the following criteria are met:

- AHI > 20 or oxygen desaturations less than 90% as determined by a nocturnal polysomnogram has been performed in an approved facility
- Cephalometric abnormalities
• (Clinically Significant) Hypopharyngeal obstruction
• CPAP/BIPAP trial over a period of time (unless RDI less than 5 cannot be achieved) or patient has immediate intolerance (true claustrophobic reaction)
• Otolaryngologist evaluation with appropriate interventions
• If UPPP performed prior to orthognathic surgery, will need to repeat sleep study demonstrating obstructive sleep apnea

**Adenotonsillectomy** may be considered **medically necessary** in pediatric patients with clinically significant OSA and hypertrophic tonsils.

**Radiofrequency ablation of palatal tissues or radiofrequency volumetric tissue reduction (Somnoplasty) does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** for simple snoring, upper airway resistance syndrome and obstructive sleep apnea syndrome.

**Uvullectomy does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** when used for the treatment of snoring.

**Midline glossectomy does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of upper airway obstruction syndrome and obstructive sleep apnea syndrome and is considered **investigational**.

**Palatal stiffening procedures**, including but not limited to, cautery assisted palatal stiffening operation, and the implantation of palatal implants, **do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered **non-covered** in the treatment of snoring alone, and are considered **investigational** as a treatment for upper airway resistance syndrome or OSA.

**Atrial pacing does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

**Repose tongue suspension system does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

**Implantable hypoglossal nerve stimulators do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered **investigational** for all indications, including but not limited to the treatment of OSA.

**Simple snoring in the absence of documented obstructive sleep apnea** is not considered a medical condition; therefore, any surgical intervention, such as LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered **non-covered**.

Medical management of OSA (i.e., CPAP, oral appliances) are discussed in medical policy #065- Medical Management of Obstructive Sleep Apnea Syndrome.
Guidelines for nocturnal polysomnography, including home studies, are discussed in medical policy #305 Polysomnography for Respiratory Sleep Disorders Testing.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
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 reviews. The most recent update was performed through October 4, 2016.

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 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). 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. The relevant trials are described in greater detail next.

Maxillomandibular Advancement
An RCT that compared maxillomandibular advancement (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 vs 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 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 (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 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 four 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 uvulopalatoplasty (LAUP) or no treatment. The LAUP procedure was repeated at one to two 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 Base Suspension**

In 2014, 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 plus UPPP, genioglossus advancement (GA) plus UPPP, and genioglossus advancement plus hyoid suspension (GAHM) plus 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 plus UPPP (8 studies, 167 patients) was...
62.3%. A success rate of 61.1% was found for GA plus UPPP (7 studies, 151 patients) and for GAHM plus UPPP (12 studies, 467 patients). The adverse effects of tongue suspension appear to be milder than GA or GAHM and are reversible. Most studies identified in this review were level IV evidence (case series).

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). 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 ≥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/m². Morbidity and complications were higher with the tongue suspension procedure compared with RFA.

RCTs are needed to determine whether adding tongue suspension to UPPP improves the net health outcome compared with treatment with UPPP alone.

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. All studies were nonrandomized.

A 2003 study by Woodson et al compared the use of multilevel RFA with the current criterion standard of continuous positive airway pressure (CPAP) in an RCT. 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. 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 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 (i.e., greater improvements were reported in those patients who had a total of five treatments).

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 per hour. 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 three 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 two-year follow-up, with a 32% reduction in ESS and a 45% reduction in RDI.

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 three-year period, 38 had UPPP alone, and 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.

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 posttreatment (4-6 months) changes in the ESS (three-point improvement in ESS for both groups), reports of snoring (one-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 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$^2$ 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 ≥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$^2$.

**Section Summary: Radiofrequency Volumetric Reduction of Palatal Tissues and Base of Tongue**
The evidence on radiofrequency volume reduction includes a meta-analysis (3 RCTs, 13 non-RCTs) and a more recent sham-controlled RCT. The meta-analysis was limited by the inclusion of uncontrolled studies. An RCT of single-stage RFA found no difference in outcomes compared to sham treatment.

**Palatal Stiffening Procedures**

**Cautery-Assisted Palatal Stiffening Operation**
There is limited evidence regarding cautery-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). 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/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 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 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.

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 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 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 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 four at both 90 days and 15 months. Subjective daytime sleepiness measured by the ESS was reduced at 90 days (11 to 7) but returned to a score of 11 at the longer follow-up. In addition to the very large loss to follow-up, questions remain about the clinical significance of a three to seven point improvement in AHI.
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 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 one patient (1.1%).

Section Summary: Palatal Stiffening Procedures

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 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.

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® 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 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 SaO2 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. 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. For the 18-month follow-up PSG, AHI and ODI scores had returned to levels observed at 12 months.

Of the original 126 patients enrolled, 116 (92%) completed 36-month follow-up and 98 (78%) patients agreed to 36-month PSG. For the remainder, the last value from the 12- or 18-month PSG was carried forward. Daily use was reported in 81% of patients. AHI was reduced from a median of 28.2 at baseline to 7.3 at 36 months, with 65% of patients meeting the definition of success described above. An AHI less than 5 events per hour was observed in 44% of patients, while an AHI less than 10 was observed in 69% of patients. An ESS score of less than 10 was reported in 15% of patients at baseline compared to 77% at 36 months. A normal Functional Outcomes of Sleep Questionnaire score (>17.9) was reported for 15% of patients at baseline compared to 63% at 36 months. Soft or no snoring as reported by the bed partner increased from
17% at baseline to 80% at 36 months. There was 1 elective device explanation due to insomnia. Tongue abrasions due to tongue movement along the teeth were successfully treated with adjustment of the stimulation or plastic dental guards.

A series of 31 patients implanted with the Apnex hypoglossal nerve stimulation system (HGNS®) was reported in 2014. Apnex Medical terminated their pivotal study and ceased operations when it was determined that the trial was unlikely to meet its primary end point.

A 2015 systematic review identified 6 case series with a total of 200 patients treated with hypoglossal nerve stimulation. No controlled trials were identified. Two series were identified on the Inspire II System and included the STAR trial previously described. Three series were identified with the HGNS system and included the study of 31 patients previously described. 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 a little over 50% (e.g., 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.

Section Summary: Hypoglossal Nerve Stimulation
The evidence on hypoglossal nerve stimulation for the treatment of OSA includes case series and 1 prospective cohort of about 100 patients followed for 3 years. For patients who had failed conservative therapy and met the inclusion criteria for AHI, BMI, and favorable pattern of palatal collapse, about two-thirds met the study definition of success. Results observed at the 12-month follow-up were maintained at 3 years. However, the comparative efficacy of this procedure relative to established OSA treatment options is uncertain. Additional study comparing hypoglossal nerve stimulation to established surgical procedures is needed to permit conclusions on the effect of this treatment on health outcomes.

Summary of Evidence
For individuals who have obstructive sleep apnea (OSA) who receive laser-assisted uvulopalatoplasty, tongue base suspension, radiofrequency volumetric reduction of palatal tissues and base of tongue, palatal stiffening procedures, or hypoglossal nerve stimulation, the evidence includes case series, cohort studies, and randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on nearly all of the minimally invasive surgical procedures reviewed herein has shown limited efficacy in patients with mild-to-moderate OSA and has not improved Apnea-Hypopnea Index (AHI) or excessive daytime sleepiness in adults with moderate-to-severe OSA. Hypoglossal nerve stimulation has shown improved outcomes in single arm studies when used in a very select group of patients. In the largest study to date, two-thirds of patients who met inclusion criteria for AHI, body mass index, and favorable pattern of palatal collapse met the study definition of success. However, the role of nerve stimulation among the surgical procedures for OSA treatment is uncertain. RCTs comparing hypoglossal nerve stimulation to conventional surgical procedures are needed to evaluate benefits and harms. The evidence is insufficient to determine the effects of the technology on health outcomes.
Because of the likelihood of adverse effects, surgery should be limited to patients who are unable to tolerate continuous positive airway pressure (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.

**Practice Guidelines and Position Statements**

**American Academy of Sleep Medicine**

AASM published practice parameters for surgical modifications of the upper airway for OSA in 2010. 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 mandibularmaxillary advancement (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 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 radiofrequency ablation 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.

**American Academy of Pediatrics**

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.

**American Academy of Otolaryngology–Head and Neck Surgery**

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, uvulopalatoplasty (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, genioglossus advancement, 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 OSA. 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. AAO-HNS notes that results appear to diminish in obese patients, and this technique should receive a weaker recommendation for these patients.

In 2011, AAO-HNS published clinical practice guidelines on polysomnography (PSG) for sleep-disordered breathing before tonsillectomy in children. In addition to recommendations for PSG (refer to policy #305 Polysomnography/Sleep Disorders Testing), 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 three years or have severe OSA (AHI ≥10, oxygen saturation nadir <80% or both).

American Society for Metabolic and Bariatric Surgery
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.

U.S. Preventive Services Task Force Recommendations
Not applicable

Key Words:
Uvulopalatopharyngoplasty, UPPP, UP-3, laser-assisted palatoplasty, LAUP, somnoplasty, radiofrequency ablation, uvulectomy, genioglossal advancement, hyoid suspension and myotomy, maxillomandibular advancement, palatal implants, Pillar™, snoring, cautery-assisted palatal stiffening, atrial pacing, PROVENT EPAP, ApniCure, Inspire II Upper Airway Stimulation System, hypoglossal nerve stimulation, Adenotonsillectomy
Approved by Governing Bodies:
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.

In 1999, 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).”

In 2014, 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®.

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:
CPT Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21120</td>
<td>Genioplasty; augmentation (autograft, allograft, prosthetic material)</td>
</tr>
<tr>
<td>21121</td>
<td>Genioplasty; sliding osteotomy, single piece</td>
</tr>
<tr>
<td>21122</td>
<td>Genioplasty; sliding osteotomies, two or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)</td>
</tr>
<tr>
<td>21123</td>
<td>Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)</td>
</tr>
<tr>
<td>21199</td>
<td>Osteotomy, mandible, segmental with genioglossal advancement</td>
</tr>
<tr>
<td>21299</td>
<td>Unlisted craniofacial and maxillofacial procedure</td>
</tr>
<tr>
<td>21685</td>
<td>Hyoid myotomy and suspension</td>
</tr>
</tbody>
</table>
Glossectomy; less than one-half tongue
Glossectomy; hemiglossectomy
Tongue base suspension, permanent suture technique
Submucosal ablation of the tongue base, radiofrequency, one or more sites, per
Resection of palate or extensive resection of lesion
Uvulectomy, excision of uvula
Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)
Unlisted procedure, Palate or Uvula
Tonsillectomy and adenoidectomy, code range
Tonsillectomy, primary or secondary, code range
Adenoidectomy, primary, code range
Adenoidectomy, secondary, code range

insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (Effective 01/01/17)
Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator (Effective 01/01/17)
Removal of chest wall respiratory sensor electrode or electrode array (Effective 01/01/17)

HCPCS Codes:
S2080 Laser-assisted Uvulopalatoplasty (LAUP)

References:


Policy History:
Medical Policy Group, January 2016 (6): Policy adopted and all information pertaining to Surgical treatment of snoring and obstructive sleep apnea transferred from medical policy #065 – Management of Obstructive Sleep Apnea to this policy.
Medical Policy Group, August 2016 (6): Policy posted, no change to medical policy statement.
Medical Policy Administration Committee, August 2016
Medical Policy Group, December 2016 (6): Removed “not a home study” from the policy statement. Added reference to medical policy #305 for guidelines for polysomnography testing.
Medical Policy Panel, December 2016
Medical Policy Group, January 2017: Updates to Description, added Adenotonsillectomy to policy statement and palatopharyngoplasty to policy statement, Key Points, Key Words, Coding, and References.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.