

## MEDICAL POLICY



<b>POLICY TITLE</b>	<b>SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA</b>
<b>POLICY NUMBER</b>	<b>MP 1.128</b>

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### I. POLICY

#### **Uvulopalatopharyngoplasty**

Uvulopalatopharyngoplasty (UPPP) may be considered **medically necessary** for the treatment of clinically significant obstructive sleep apnea syndrome (OSA) or upper airway resistance syndrome (UARS) in appropriately selected adult patients who have not responded to or do not tolerate positive airway pressure (PAP) therapy.

Clinically significant OSA is defined as those patients who have:

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

Clinically significant UARS is defined as those patients who have:

- Greater than 10 EEG arousals per hour **OR**
- Presence of abnormally negative intrathoracic pressures (i.e., more negative than 10 cm) in conjunction with the EEG arousals

Note: The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram.

#### **Hyoid Suspension, Surgical Modification of Tongue, Maxillofacial Surgery**

Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered **medically necessary** in appropriately selected adult patients with clinically significant OSA, upper airway resistance syndrome, or objective documentation of hypopharyngeal obstruction who have not responded to or do not tolerate PAP therapy.

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Clinically significant OSA is defined as those patients who have:

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

Clinically significant UARS is defined as those patients who have:

- Greater than 10 EEG arousals per hour **OR**
- Presence of abnormally negative intrathoracic pressures (i.e., more negative than 10 cm) in conjunction with the EEG arousals

**Note:** The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram

### Adenotonsillectomy

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

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

### Other procedures

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

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

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\*There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with the above surgical procedures.

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

### Policy Guidelines

Clinically significant obstructive sleep apnea (OSA) is defined as those adult patients who have:

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

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

The presentation of OSA in pediatric patients may differ from that of adults. OSA in pediatric patients is defined as those who have:

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

Clinically significant upper airway resistance syndrome (UARS) is defined as greater than 10 EEG arousals per hour. The presence of abnormally negative intrathoracic pressures (i.e., more negative than 10 cm) in conjunction with the EEG arousals supports the

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diagnosis. The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram. Objective evidence of hypopharyngeal obstruction is documented by either fiberoptic endoscopy or cephalometric radiographs.

### *Cross-references*

MP-2.045 Diagnosis and Medical Management of Obstructive Sleep Apnea

MP-2.062 Temporomandibular Joint Dysfunction

MP-1.101 Orthognathic Surgery

## II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids

[N] Indemnity

[N] PPO

[N] SpecialCare

[N] HMO

[N] POS

[N] SeniorBlue HMO

[Y] FEP PPO\*

[N] SeniorBlue PPO

\* Refer to FEP Medical Policy Manual MP-1.01.101 Surgical Treatment of Snoring and Obstructive Sleep Apnea. The FEP Medical Policy manual can be found at:

<http://bluewebportal.bcbs.com/landingpagelevel3/504100?docId=23980>

## III. DESCRIPTION/BACKGROUND

. This policy addresses the various surgical procedures that have been evaluated for the treatment of adult and pediatric patients with OSA.

Obstructive sleep apnea (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. 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.

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OSA may also be associated with a variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. Obstruction anywhere along the upper airway can result in apnea. Therefore, OSA is associated with a heterogeneous group of anatomic variants producing obstruction.

The hallmark symptom of OSA is excessive daytime sleepiness and the typical clinical sign of OSA is snoring, which can abruptly cease and be followed by gasping associated with a brief arousal from sleep. The snoring resumes when the patient falls back to sleep, and the cycle of snoring/apnea/arousal may be repeated as frequently as every minute throughout the night. Sleep fragmentation associated with the repeated arousal during sleep can lead to impairment of daytime activity. For example, adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, i.e., cars, trucks, or heavy equipment. OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

***Diagnosis***

The final diagnosis of OSA rests on a combination of clinical evaluation and objective criteria to identify those levels of obstruction that are considered to be clinically significant. The gold standard diagnostic test for sleep disorders is considered a polysomnogram, which includes sleep staging to assess arousals from sleep, and determination of the frequency of apneas and hypopneas from channels measuring oxygen desaturation, respiratory airflow and respiratory effort. An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. Obstructive hypopnea is a > 30% reduction of air exchange with an associated fall in oxygen saturation of at least 3-4%. 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 apnea/hypopnea index (AHI) is defined as the total number of apneas and hypopneas per hour of sleep. The respiratory disturbance index (RDI) may be defined as the number of apneas, hypopneas and RERAs per hour of sleep. When sleep onset and offset are unknown (e.g., in home sleep studies),

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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 >5 and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI greater than or equal to 15 is typically considered moderate OSA, while an AHI greater than 50 is considered severe OSA. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds. Hypopneas are scored by a 50% or greater drop in nasal pressure and either a >3% decrease in oxygen saturation or an associated arousal. In pediatric patients, an AHI >1.5 is considered abnormal and an AHI of 15 or more is considered severe.

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

### ***Treatment***

Nonsurgical treatment for OSA or UARS includes CPAP or orthodontic repositioning devices. Traditional surgeries for OSA or UARS include uvulopalatopharyngoplasty (UPPP) and a variety of maxillofacial surgeries such as mandibular-maxillary advancement (MMA). UPPP involves surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. The amount of tissue removed is individualized for each patient as determined by the potential space and width of the tonsillar pillar mucosa between the 2 palatal arches. The UPPP enlarges the oropharynx but cannot correct obstructions in the hypopharynx. Thus, patients who fail UPPP may be candidates for additional procedures, depending on the site of obstruction. Additional procedures include hyoid suspensions, maxillary and mandibular osteotomies, or modification of the tongue. Fiberoptic endoscopy and/or cephalometric measurements have been used as methods to identify hypopharyngeal obstruction in these patients. The first-line treatment in children is usually adenotonsillectomy. Minimally invasive surgical approaches being evaluated for OSA in adults include the following:

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### ***Laser-assisted Uvulopalatoplasty (LAUP)***

LAUP is an outpatient alternative that has been proposed as a treatment of snoring with or without associated OSA. In this procedure, superficial palatal tissues are sequentially reshaped using a carbon dioxide laser. The extent of the surgery is typically different than standard UPPP, since only part of the uvula and associated soft-palate tissues are reshaped. The procedure, as initially described, does not remove or alter tonsils or lateral pharyngeal wall tissues. The patient undergoes from 3 to 7 sessions at 3- to 4-week intervals. One purported advantage of LAUP is that the amount of tissue ablated can be titrated such that the treatment can be discontinued once snoring is eliminated. LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, which raises its own issues of safety and, in particular, effectiveness.

### ***Radiofrequency Ablation of Palatal Tissues and the Tongue***

Radiofrequency ablation 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, radiofrequency ablation appears to be growing in popularity as an alternative to LAUP. In some situations, radiofrequency of the soft palate and base of tongue are performed together as a multilevel procedure.

### ***Tongue Base Suspension***

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

### ***Palatal Stiffening***

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

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### Regulatory Status

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

The Repose™ Bone Screw System (Influence, San Francisco, CA) was cleared for marketing through the 510(k) process in 1999 with intended use for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is indicated for the treatment of OSA and/or snoring.

The Pillar™ Palatal Implant System (Restore Medical, St. Paul, MN) is an implantable device that has been cleared for marketing through the FDA 510(k) process. The labeled indication of the device is as follows: “The Pillar™ Palatal Implant System is intended for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (obstructive sleep apnea).”

## IV. RATIONALE

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

### Literature Review

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

A 2009 systematic review by Franklin and colleagues evaluated benefits and adverse effects of surgery for snoring and OSA. (4) The authors found only a small number of randomized controlled trials (RCTs) that assessed surgical procedures for snoring or sleep apnea. Key findings are as follows:

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- Results from 45 studies reporting adverse events revealed persistent side effects after uvulopalatoplasty (UPP) and uvulopalatopharyngoplasty (UPPP) in about half the patients. Difficulty swallowing, globus sensation, and voice changes were especially common. The authors concluded that additional research with RCTs of surgery other than UPP and UPPP is needed, as these surgical procedures are related to a high risk of side effects, especially difficulty swallowing.
- Four RCTs, rated as high quality, were identified for laser-assisted palatoplasty (LAUP) and radiofrequency ablation (RFA). (5-8) Study results were mixed and inconclusive for apnea/hypopnea index (AHI), and showed no benefit on daytime sleepiness or quality of life. Interpretation of this result is limited by the inclusion of studies with one-stage procedures and subjects whose main symptom was disruptive snoring. (7) The relevant trials are described in greater detail below.

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

*Adenotonsillectomy:* Three systematic reviews were published in 2009 on tonsillectomy for obstructive sleep apnea in children. (10-12) Kuhle and colleagues reviewed randomized trials on interventions for children with OSA. (10, 11) The single RCT on surgical interventions that was identified compared RFA of the tonsils with conventional adenotonsillectomy. Both procedures were found to reduce the respiratory disturbance index (RDI) (from 7.7 and 7.6/h to 0.3 and 1.6/h, respectively). Friedman et al. performed a meta-analysis of 23 studies (1,079 children with a mean age of 6.5 years) to evaluate success rates of tonsillectomy and adenoidectomy for pediatric OSA. (11) The mean preoperative AHI was 18.6 and the mean postoperative AHI was 4.9, with a mean change after surgery of 12.4 events per hour. Although limited by heterogeneity, the success rate was found to be 66% when success was defined as an AHI less than 5 and 60% when success was defined as an AHI less than 1.

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Further analysis found that the success rate (AHI <5) was only 39% in children with co-morbidities such as obesity compared to a 74% success rate observed in uncomplicated patients. Due to likely publication bias, the authors concluded that these rates should be considered an upper limit of success. Costa and Mitchell also reported lower efficacy in obese children from their meta-analysis of 4 studies reporting on this population. (12) The mean pre- and postoperative AHI was 29.4 and 10.3, respectively. Following adenotonsillectomy, 49% of obese children had a postoperative AHI less than 5, 25% had a postoperative AHI less than 2, and 12% had a postoperative AHI less than 1.

*Laser-Assisted Uvulopalatoplasty (LAUP):* Ferguson and colleagues reported on a trial that randomized 45 subjects with mild to moderate sleep apnea (defined as an AHI ranging between 10 and 27 per hour) to either LAUP or no treatment. (5) The LAUP procedure was repeated at 1- to 2-month intervals until either the snoring was significantly reduced, no more tissue could safely be removed, or the patient refused further procedures. The primary outcome measurement was the reduction in AHI in the LAUP group versus the control group. An AHI of less than 10 was considered a successful treatment. In the treatment group, 24% were considered treatment successes and 76% were failures. In the control group (who received no therapy), 16.7% were considered treatment successes. The authors concluded that LAUP can be effective in some patients, but the reduction in AHI and the level of symptomatic improvement were minor overall.

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

In 2008, Farrar a OSA in patients with a RDI of 5 or more. (13) Sixteen ere nonrandomized studies met the inclusion criteria; 3 were randomized and 13 were nonrandomized. Six studies treated both the base of the tongue and the soft palate, 2 treated the soft palate only, and 8 ablated the base of the tongue only. The population was in the overweight, but not obese, category, with a mean BMI of 28.5. In half of the studies, the average baseline RDI was less than 30, and in 6 of the studies, the average baseline Epworth Sleepiness Scale (ESS) was less than 10. The meta-analysis indicated a 31% reduction in both ESS and RDI. The lowest oxygen saturation level was not improved by RFA. The mean number of treatments required for patient satisfaction was 3.7 for the soft palate, 4.3 for the base of the tongue, and 4.8 for both sites (range of 3 to 7). Complications were noted in 4% of patients; 2 tongue abscesses progressed to airway obstruction requiring tracheotomy. Only 2 of the studies provided 2-year follow-up, with a 32% reduction in ESS and a 45% reduction in RDI. The number of patients who were successfully treated (e.g., 50% reduction in RDI) was not reported. This meta-

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analysis is limited by the inclusion of poor quality uncontrolled studies. Higher quality studies are described below.

A single-blinded RCT of single-stage radiofrequency surgery of the soft palate was reported in 2009. (14) Thirty-two patients with mild OSA (AHI between 5 and 15), habitual snoring, and excessive daytime sleepiness according to subjective patient history, were randomized to a single session of RFA or sham ablation. There was no difference between the groups for baseline to post-treatment (4-6 months) changes in the ESS (3-point improvement in ESS for both groups), reports of snoring (1 point improvement in both groups), AHI (no clinically significant change), or any other outcome measure. None of the patients reported any treatment-related symptoms or complications 4 months after treatment. Results of this small single-blinded RCT indicate that single-stage RFA of the soft palate is not effective for the treatment of mild OSA.

An RCT from 2009 compared efficacy and side effects of 2 tongue-based procedures (RFA or tongue-base suspension) when combined with UPPP in patients with moderate-to -severe sleep apnea (AHI  $\geq 15$ ). (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, success rates for the combined procedures (defined as an  $\geq 50\%$  reduction and final AHI  $< 15$ ) were 51% to 57%, respectively. BMI was the main predictor of success, with success rates of only 10% to 12.5% in patients with a BMI between 30 and  $< 35$  kg/mg<sup>2</sup>. Morbidity was higher with the tongue suspension procedure.

A 2008 retrospective cohort study assessed the incremental value of RFA of the tongue in combination with UPPP. (16) All patients with both palatal and retroglossal obstruction, an RDI between 5 and 50, and no previous OSA surgery were included in the study. Seventy-five patients meeting the inclusion criteria had been treated with UPPP during the 3-year period, 38 had UPPP alone, 37 had UPPP plus RFA. The groups were comparable for age, gender, BMI, AHI, and mean oxygen saturation (SaO<sub>2</sub>); however, no details were provided regarding the choice of procedure. With surgical success rate defined as more than 50% reduction of the AHI and AHI below 20, the success rate was 42% with UPPP alone and 49% with RFA (not significantly different). Two patients had an additional RFA treatment. No major complications were observed. The authors concluded that the addition of RFA to UPPP resulted in only limited improvement, but there was no major downside to it.

A 2003 study by Woodson and colleagues compared the use of multilevel RFA with the current gold standard of continuous positive airway pressure (CPAP) in an RCT. (6) The study included patients with mild obesity levels (BMI of 34 or greater) who had mild to moderate sleep apnea with an AHI between 10 and 30. Statistically significant improvement was noted with RFA and CPAP over placebo in OSA-specific quality of life using the Functional Outcomes of Sleep Questionnaire. However, the small size of the trial resulted in most

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outcomes not being statistically significant. The same group of authors reported a further subgroup analysis from the same trial, focusing on the 26 patients randomized to the RFA arm of the trial to determine whether additional treatments improved outcomes. (17) Specifically, the authors focused on multi-level treatments on various combinations of palatal and tongue tissues. The authors reported that greater improvements in quality of life were reported for those patients who had a total of 5 treatments compared to 3. Another subgroup analysis focused on multi-level treatments in 26 patients. (18) This subgroup likely contains overlapping patients with the previous report, and the results were similar; i.e., greater improvements were reported in those patients who had a total of 5 treatments.

**Palatal Stiffening Procedures**

*Cautery-Assisted Palatal Stiffening Operation (CAPSO):* There is limited evidence regarding CAPSO in patients with clinically significant OSA; most studies on CAPSO focus on patients with simple snoring ( $AHI < 5$ ) or mild sleep apnea ( $AHI < 15$ ). (19, 20) In 2000, Wassmuth and colleagues reported a case series of 25 patients with OSA who underwent CAPSO. (21) Responders were defined as patients who had a reduction in AHI of at least 50%. Mean AHI improved from  $25.1 \pm 12.9$  to  $16.6 \pm 15.0$ . The broad confidence intervals limit interpretation of these data.

*Palatal Implants:* In a 2008 trial by Steward et al., 100 patients with mild to moderate OSA and suspected retropalatal obstruction were randomly assigned to palatal implants or sham placebo. (22) Patients with BMI greater than  $32 \text{ kg/m}^2$  were excluded from the study. About 1,000 patients were evaluated to identify the 100 study patients. At 3 months' follow-up, the average AHI increased in both groups from a baseline of about 17, although the increase was greater in the placebo group (8.9 vs. 2.9, respectively). A reduction in AHI by at least 50% or to below 20 was more common in the implant group (26% vs. 10%, respectively;  $p=0.05$ ). Improvement in ESS did not differ from that of sham ( $p=0.62$ ). Partial implant extrusion occurred in 2 patients (4%).

Friedman et al. reported an industry-sponsored randomized double-blind, sham-controlled trial of palatal implants in 62 patients with symptoms of OSA. (23) Other inclusion criteria included: Friedman tongue position I, II, or III; diagnosis of mild to moderate OSA ( $AHI \geq 5$  and  $< 40$ ) on baseline PSG; a soft palate of 2 cm or more but less than 3.5 cm; and body mass index (BMI) less than  $32 \text{ kg/m}^2$ . AHI at baseline was 23.8 events per hour in the implant group and 20.1 in controls. Seven patients did not return for repeat PSG and were considered treatment failures in the intent-to-treat (ITT) analysis. At 3-month follow-up, the AHI improved to 15.9 events per hour in the implant group but did not change significantly in the controls (21.0). The ESS improved from 12.7 to 10.2 in the implant group and did not change significantly in the controls (from 11.7 to 11.1). With success defined as an AHI reduction of 50% or more and AHI less than 20, palatal implantation resulted in the successful treatment of

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

In 2012, Maurer and colleagues reported a randomized, double-blind, sham-controlled trial of the Pillar palatal implant in 20 patients with mild to moderate OSA due to palatal obstruction. (24) At 90 days, the AHI in the treatment group improved from 19.1 to 8.2 events per hour and lowest oxygen saturation improved from 82.8 to 88.3%. These measures did not improve significantly in the control group, and there was no significant difference in outcomes between the implant and control groups in this small trial. The ESS did not improve significantly in either group.

There are also uncontrolled series of patients treated with palatal implants. For example, Walker and colleagues published 90-day and 15-month follow-up from a multicenter study on palatal implants (Pillar System) in 63 subjects. (25, 26) The AHI decreased from a baseline of 25 to 22 in the 53 patients (84%) who were evaluated at 90 days. Twenty-two patients (35%) were available for the follow-up study; 13 had shown a decrease in AHI (from a baseline of 20 to 13) at 90 days. Of these, 10 (77% of the 13) maintained the decrease at 15 months. The 9 patients whose AHI had not improved at 90 days had no subsequent improvement at the extended follow-up. Mean snoring was rated as 8 at baseline (visual analogue scale [VAS]), and 4 at both 90 days and 15 months. Subjective daytime sleepiness measured by the ESS was reduced at 90 days (from 11 to 7) but returned to a score of 11 at the longer follow-up. In addition to the very large loss to follow-up, questions remain about the clinical significance of a 3- to 7-point improvement in AHI.

Neruntarat reported a case series with a minimum of 24-month follow-up. (27) This study included 92 patients with mild to moderate OSA ( $AHI \leq 30$  with daytime sleepiness or disturbed sleep) who had received palatal implants after failed medical management. At baseline, the mean AHI was 21.7 events per hour, and the lowest oxygen saturation was 87.4%. At mean 28.9-month follow-up, the AHI had decreased to 10.8, and the lowest oxygen saturation improved to 89.2%. Sleep efficiency improved from 80.6% to 87.2%, and the ESS score improved from a mean of 12.3 to 7.9. Implant extrusion occurred in 7 patients (7.6%), and palatal abscess occurred in 1 patient (1.1%).

**Conclusions:** The literature on palatal implants consists of 3 randomized controlled trials and additional case series with medium-term follow-up. Evidence from sham-controlled trials shows a statistically significant but modest reduction in AHI and improvement in lowest oxygen saturation compared to placebo, with limited effects on daytime sleepiness. Additional study is needed to determine whether there is a defined subset of patients who might benefit from this procedure. Studies with longer-term follow-up are also needed to evaluate the potential for extrusion of the implants at longer time intervals.

### Summary

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POLICY TITLE	SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA
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There is a great range of severity of OSA, with symptoms ranging from snoring only to severe excessive daytime sleepiness or hypertension. If OSA is considered mild (AHI between 5 and 15) and snoring is the only manifestation, intervention is considered not medically necessary.

Adenotonsillectomy may be considered medically necessary in pediatric patients with OSA. Standard surgical procedures (i.e., UPPP and maxillofacial procedures) have been found to improve symptoms in adult patients with clinically significant OSA. Due to the likelihood of adverse effects, surgery should be limited to patients who are unable to tolerate CPAP.

Minimally invasive surgical procedures have limited efficacy in patients with mild to moderate OSA and have not been shown to improve AHI or excessive daytime sleepiness in adult patients with moderate to severe OSA. These are considered investigational.

### Practice Guidelines and Position Statements

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

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

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evaluation, which includes a clinical evaluation and an objective measure of the presence and severity of sleep-disordered breathing and oxygen saturation. However, little guidance was available in the medical literature to recommend any particular monitoring strategy. The optimal interval and duration of this follow-up are also not clear from the available literature.

In 2011, the American Academy of Otolaryngology – Head and Neck Surgery published clinical practice guidelines on polysomnography (PSG) for sleep-disordered breathing prior to tonsillectomy in children. (32) In addition to recommendations for PSG, 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  $\geq 10$ , oxygen saturation nadir  $< 80\%$  or both).

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

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

## V. DEFINITIONS

**510 (K)** is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

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**APNEA** is the cessation of respiration for at least ten (10) seconds.

**CLINICALLY SIGNIFICANT OBSTRUCTIVE SLEEP APNEA SYNDROME (OSA) (ADULT PATIENTS)** is defined as those patients who meet any of the following criteria:

- An apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to fifteen ( $\geq 15$ ) events per hour **OR**
- The AHI or RDI is greater than or equal to five ( $\geq 5$ ) and less than or equal to fourteen ( $\leq 14$ ) 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.

**CLINICALLY SIGNIFICANT OBSTRUCTIVE SLEEP APNEA SYNDROME (OSA) (PEDIATRIC PATIENTS)** Is defined as those pediatric patients who meet any of the following criteria

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

**ELECTROENCEPHALOGRAPH (EEG)** is the tracing of the electrical activity of the brain by an electroencephalograph.

**EPWORTH SLEEPINESS SCALE** is a self-administered questionnaire that asks patients their likelihood of falling asleep in eight situations ranked from zero (never doze) to three (high chance of dozing). The numbers are then added together to score between zero and twenty-four. The eight situations are as follows:

1. Sitting and reading;
2. Watching TV;
3. Sitting inactive in a public place, i.e., theater;
4. As a passenger in a car for one hour without a break;
5. Lying down to rest in the afternoon when circumstances permit;
6. Sitting and talking to someone;
7. Sitting quietly after a lunch without alcohol; and
8. In a car, while stopped for a few minutes in traffic.

**HYPOPNEA** is the reduction but not the cessation of air exchange.

**INTRA-ORAL APPLIANCE** is a device placed in the mouth to correct or alleviate malocclusion.

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**MULTIPLE SLEEP LATENCY TESTS** involve repeated measurement of sleep latency, which is the time to the onset of sleep. The test is performed in the daytime under standardized conditions following quantified nocturnal sleep. Usually two to six tests are performed, one testing every two hours, to measure daytime sleep tendency.

**POLYSOMNOGRAPHY** refers to the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for six or more hours with physician review, interpretation and report. In addition, polysomnography has sleep staging, which includes an electroencephalogram (EEG), electro-oculogram (EOG), and submental electromyogram (EMG).

**UPPER AIRWAY RESISTANCE SYNDROME (UARS)** is defined as: Greater than ten (10) alpha EEG arousals per hour. The presence of abnormally negative intrathoracic pressures (i.e., more negative than -10 cm) in conjunction with the EEG arousals supports the diagnosis. The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram.

## VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

## VII. DISCLAIMER

*Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## VIII. REFERENCES

1. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Surgical management of sleep apnea. TEC Assessments 1995; Volume 10, Tab 32.*

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2. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Radiofrequency volumetric tissue reduction for sleep-related breathing disorders. TEC Assessments 2000; Volume 15, Tab 15.*
3. *Balk EM, Moorthy D, Obadan NO et al. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32 (Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-100551) AHRQ Publication No. 11-EHC052-EF. Rockville MD: Agency for Healthcare Research and Quality Jul 2011.*
4. *Franklin KA, Anttila H, Axelsson S et al. Effects and side-effects of surgery for snoring and obstructive sleep apnea--a systematic review. Sleep 2009; 32(1):27-36.*
5. *Ferguson KA, Heighway K, Ruby RR. A randomized trial of laser-assisted uvulopalatoplasty in the treatment of mild obstructive sleep apnea. Am J Respir Crit Care Med 2003; 167(1):15-9.*
6. *Woodson BT, Steward DL, Weaver EM et al. A randomized trial of temperature-controlled radiofrequency, continuous positive airway pressure, and placebo for obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2003; 128(6):848-61.*
7. *Larrosa F, Hernandez L, Morello A et al. Laser-assisted uvulopalatoplasty for snoring: does it meet the expectations? Eur Respir J 2004; 24(1):66-70.*
8. *Stuck BA, Sauter A, Hormann K et al. Radiofrequency surgery of the soft palate in the treatment of snoring. A placebo-controlled trial. Sleep 2005; 28(7):847-50.*
9. *Vicini C, Dallan I, Campanini A et al. Surgery vs ventilation in adult severe obstructive sleep apnea syndrome. Am J Otolaryngol 2010; 31(1):14-20.*
10. *Kuhle S, Urschitz MS, Eitner S et al. Interventions for obstructive sleep apnea in children: a systematic review. Sleep Med Rev 2009; 13(2):123-31.*
11. *Friedman M, Wilson M, Lin HC et al. Updated systematic review of tonsillectomy and adenoidectomy for treatment of pediatric obstructive sleep apnea/hypopnea syndrome. Otolaryngol Head Neck Surg 2009; 140(6):800-8.*
12. *Costa DJ, Mitchell R. Adenotonsillectomy for obstructive sleep apnea in obese children: a meta-analysis. Otolaryngol Head Neck Surg 2009; 140(4):455-60.*
13. *Farrar J, Ryan J, Oliver E et al. Radiofrequency ablation for the treatment of obstructive sleep apnea: a meta-analysis. Laryngoscope 2008; 118(10):1878-83.*
14. *Back LJ, Liukko T, Rantanen I et al. Radiofrequency surgery of the soft palate in the treatment of mild obstructive sleep apnea is not effective as a single-stage procedure: A randomized single-blinded placebo-controlled trial. Laryngoscope 2009; 119(8):1621-7.*
15. *Fernandez-Julian E, Munoz N, Achiques MT et al. Randomized study comparing two tongue base surgeries for moderate to severe obstructive sleep apnea syndrome. Otolaryngol Head Neck Surg 2009; 140(6):917-23.*

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16. van den Broek E, Richard W, van Tinteren H et al. UPPP combined with radiofrequency thermotherapy of the tongue base for the treatment of obstructive sleep apnea syndrome. *Eur Arch Otorhinolaryngol* 2008; 265(11):1361-5.
17. Steward DL, Weaver EM, Woodson BT. A comparison of radiofrequency treatment schemes for obstructive sleep apnea syndrome. *Otolaryngol Head Neck Surg* 2004; 130(5):579-85.
18. Steward DL. Effectiveness of multilevel (tongue and palate) radiofrequency tissue ablation for patients with obstructive sleep apnea syndrome. *Laryngoscope* 2004; 114(12):2073-84.
19. Mair EA, Day RH. Cautery-assisted palatal stiffening operation. *Otolaryngol Head Neck Surg* 2000; 122(4):547-56.
20. Pang KP, Terris DJ. Modified cautery-assisted palatal stiffening operation: new method for treating snoring and mild obstructive sleep apnea. *Otolaryngol Head Neck Surg* 2007; 136(5):823-6.
21. Wassmuth Z, Mair E, Loube D et al. Cautery-assisted palatal stiffening operation for the treatment of obstructive sleep apnea syndrome. *Otolaryngol Head Neck Surg* 2000; 123(1 Pt 1):55-60.
22. Steward DL, Huntley TC, Woodson BT et al. Palate implants for obstructive sleep apnea: multi-institution, randomized, placebo-controlled study. *Otolaryngol Head Neck Surg* 2008; 139(4):506-10.
23. Friedman M, Schalch P, Lin HC et al. Palatal implants for the treatment of snoring and obstructive sleep apnea/hypopnea syndrome. *Otolaryngol Head Neck Surg* 2008; 138(2):209-16.
24. Maurer JT, Sommer JU, Hein G et al. Palatal implants in the treatment of obstructive sleep apnea: a randomised, placebo-controlled single-centre trial. *Eur Arch Otorhinolaryngol* 2012; 269(7):1851-6.
25. Walker RP, Levine HL, Hopp ML et al. Palatal implants: a new approach for the treatment of obstructive sleep apnea. *Otolaryngol Head Neck Surg* 2006; 135(4):549-54.
26. Walker RP, Levine HL, Hopp ML et al. Extended follow-up of palatal implants for OSA treatment. *Otolaryngol Head Neck Surg* 2007; 137(5):822-7.
27. Neruntarat C. Long-term results of palatal implants for obstructive sleep apnea. *Eur Arch Otorhinolaryngol* 2011; 268(7):1077-80.
28. Littner M, Kushida CA, Hartse K et al. Practice parameters for the use of laser-assisted uvulopalatoplasty: an update for 2000. *Sleep* 2001; 24(5):603-19.
29. Epstein LJ, Kristo D, Strollo PJ, Jr. et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med* 2009; 5(3):263-76.
30. Aurora RN, Casey KR, Kristo D et al. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. *Sleep* 2010; 33(10):1408-13.

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31. Caples SM, Rowley JA, Prinsell JR et al. *Surgical modifications of the upper airway for obstructive sleep apnea in adults: a systematic review and meta-analysis*. Sleep 2010; 33(10):1396-407.
32. Roland PS, Rosenfeld RM, Brooks LJ et al. *Clinical practice guideline: Polysomnography for sleep-disordered breathing prior to tonsillectomy in children*. Otolaryngol Head Neck Surg 2011; 145(1 Suppl):S1-15.
33. American Academy of Pediatrics. Section on Pediatric Pulmonology. Subcommittee on Obstructive Sleep Apnea Syndrome. *Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome*. Pediatrics 2002; 109(4):704-12.
34. American Academy of Otolaryngology Head and Neck Surgery. *Surgical Management of Obstructive Sleep Apnea*. 1998. Available online at: <http://www.entnet.org/Practice/policySurgicalMgmtApnea.cfm>. Last accessed April, 2013.
35. Centers for Medicare and Medicaid. *Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA)* (CAG-00093N) [Website]: [http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=19&ver=7&NcaName=Continuous+Positive+Airway+Pressure+\(CPAP\)+Therapy+for+Obstructive+Sleep+Apnea+\(OSA\)&TAId=50&bc=AAAAAAAEEAAA&..](http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=19&ver=7&NcaName=Continuous+Positive+Airway+Pressure+(CPAP)+Therapy+for+Obstructive+Sleep+Apnea+(OSA)&TAId=50&bc=AAAAAAAEEAAA&..) Accessed July 19, 2013.
36. Mosby's Medical, Nursing, & Allied Health Dictionary, 6th edition.
37. Taber's Cyclopedic Medical Dictionary, 19th edition.

## IX. CODING INFORMATION

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

### Covered when medically necessary:

CPT Codes®								
21110	21121	21122	21123	21141	21142	21143	21145	21146
21147	21195	21196	21199	21299	21685	41120	41130	41530
41599	42145	42299	42820	42821	42825	42826	42830	42831
42835	42836	42999						

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<b>ICD-9-CM Diagnosis Code*</b>	<b>Description</b>
278.01	MORBID OBESITY
278.02	OVERWEIGHT
307.41	TRANSIENT DISORDER OF INITIATING OR MAINTAINING SLEEP
307.42	PERSISTENT DISORDER OF INITIATING OR MAINTAINING SLEEP
307.43	TRANSIENT DISORDER OF INITIATING OR MAINTAINING WAKEFULNESS
307.44	PERSISTENT DISORDER OF INITIATING OR MAINTAINING WAKEFULNESS
307.45	CIRCADIAN RHYTHM SLEEP DISORDER OF NONORGANIC ORIGIN
307.46	SLEEP AROUSAL DISORDER
307.47	OTHER DYSFUNCTIONS OF SLEEP STAGES OR AROUSAL FROM SLEEP
307.48	REPETITIVE INTRUSIONS OF SLEEP
327.0	ORGANIC SLEEP DISORDERS
327.00	ORGANIC INSOMNIA, UNSPECIFIED
327.01	INSOMNIA DUE TO MEDICAL CONDITION CLASSIFIED ELSEWHERE
327.09	OTHER ORGANIC INSOMNIA
327.1	ORGANIC DISORDER EXCESS SOMNOLENCE
327.10	ORGANIC HYPERSOMNIA, UNSPECIFIED
327.11	IDIOPATHIC HYPERSOMNIA WITH LONG SLEEP TIME
327.13	RECURRENT HYPERSOMNIA
327.14	HYPERSOMNIA DUE TO MEDICAL CONDITION CLASSIFIED ELSEWHERE
327.19	OTHER ORGANIC HYPERSOMNIA
327.2	ORGANIC SLEEP APNEA
327.20	ORGANIC SLEEP APNEA, UNSPECIFIED
327.21	PRIMARY CENTRAL SLEEP APNEA
327.22	HIGH ALTITUDE PERIODIC BREATHING
327.23	OBSTRUCTIVE SLEEP APNEA (ADULT) (PEDIATRIC)
327.24	IDIOPATHIC SLEEP RELATED NONOBSTRUCTIVE ALVEOLAR HYPOVENTILATION
327.25	CONGENITAL CENTRAL ALVEOLAR HYPOVENTILATION SYNDROME
327.26	SLEEP RELATED HYPOVENTILATION/HYPOXEMIA IN CONDITIONS CLASSIFIABLE ELSEWHERE
327.27	CENTRAL SLEEP APNEA IN CONDITIONS CLASSIFIED ELSEWHERE
327.29	OTHER ORGANIC SLEEP APNEA
327.3	CIRCADIAN RHYTHM SLEEP DISORDER

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<b>ICD-9-CM Diagnosis Code*</b>	<b>Description</b>
327.30	CIRCADIAN RHYTHM SLEEP DISORDER, UNSPECIFIED
327.31	CIRCADIAN RHYTHM SLEEP DISORDER, DELAYED SLEEP PHASE TYPE
327.32	CIRCADIAN RHYTHM SLEEP DISORDER, ADVANCED SLEEP PHASE TYPE
327.33	CIRCADIAN RHYTHM SLEEP DISORDER, IRREGULAR SLEEP-WAKE TYPE
327.34	CIRCADIAN RHYTHM SLEEP DISORDER, FREE-RUNNING TYPE
327.39	OTHER CIRCADIAN RHYTHM SLEEP DISORDER
327.4	ORGANIC PARASOMNIA
327.40	ORGANIC PARASOMNIA, UNSPECIFIED
327.41	CONFUSIONAL AROUSALS
327.42	REM SLEEP BEHAVIOR DISORDER
327.44	PARASOMNIA IN CONDITIONS CLASSIFIED ELSEWHERE
327.49	OTHER ORGANIC PARASOMNIA
327.5	ORGANIC SLEEP RELATED MOVEMENT DISORDERS
327.59	OTHER ORGANIC SLEEP RELATED MOVEMENT DISORDERS
327.8	OTHER ORGANIC SLEEP DISORDERS
333.2	MYOCLONUS
333.94	RESTLESS LEGS SYNDROME [RLS]
347.	CATAPLEXY AND NARCOLEPSY
347.0	NARCOLEPSY
347.00	NARCOLEPSY, WITHOUT CATAPLEXY
347.01	NARCOLEPSY, WITH CATAPLEXY
347.1	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE
347.10	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE, WITHOUT CATAPLEXY
347.11	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE, WITH CATAPLEXY
414.0	CORONARY ATHEROSCLEROSIS
414.8	OTHER SPECIFIED FORMS OF CHRONIC ISCHEMIC HEART DISEASE
414.9	UNSPECIFIED CHRONIC ISCHEMIC HEART DISEASE
780.09	OTHER ALTERATION OF CONSCIOUSNESS
780.5	SLEEP DISTURBANCES
780.51	INSOMNIA WITH SLEEP APNEA, UNSPECIFIED
780.51	INSOMNIA WITH SLEEP APNEA, UNSPECIFIED
780.52	INSOMNIA, UNSPECIFIED
780.53	HYPERSOMNIA WITH SLEEP APNEA, UNSPECIFIED

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<b>ICD-9-CM Diagnosis Code*</b>	<b>Description</b>
780.54	HYPERSOMNIA, UNSPECIFIED
780.55	DISRUPTION OF 24 HOUR SLEEP WAKE CYCLE, UNSPECIFIED
780.56	DYSFUNCTIONS ASSOCIATED WITH SLEEP STAGES OR AROUSAL FROM SLEEP
780.57	UNSPECIFIED SLEEP APNEA
780.58	SLEEP RELATED MOVEMENT DISORDER, UNSPECIFIED
780.59	OTHER SLEEP DISTURBANCES
786.09	OTHER DYSPNEA AND RESPIRATORY ABNORMALITIES
799.01	ASPHYXIA
799.02	HYPOXEMIA
V12.54	TRANSIENT ISCHEMIC ATTACK (TIA), AND CEREBRAL INFARCTION WITHOUT RESIDUAL DEFICITS

\*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

**Investigational; therefore not covered:**

<b>CPT Codes®</b>							
41512	41530						

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**The following code is considered investigational when used for the sole or adjunctive treatment of obstructive sleep apnea (OSA) or upper airway resistance syndrome as outlined in the policy section; therefore not covered:**

<b>HCPCS Code</b>	<b>Description</b>
S2080	LASER-ASSISTED UVULOPALATOPLASTY (LAUP)

**The following ICD-10 diagnosis codes will be effective October 1, 2014**

<b>ICD-10-CM Diagnosis Code*</b>	<b>Description</b>
E66.01	Morbid (severe) obesity due to excess calories
E66.3	Overweight
F51.09	Other insomnia not due to a substance or known physiological condition
F51.09	Other insomnia not due to a substance or known physiological condition

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<b>ICD-10-CM Diagnosis Code*</b>	<b>Description</b>
F51.01	Primary insomnia
F51.19	Other hypersomnia not due to a substance or known physiological condition
F51.12	Insufficient sleep syndrome
F51.19	Other hypersomnia not due to a substance or known physiological condition
F51.11	Primary hypersomnia
F51.8	Other sleep disorders not due to a substance or known physiological condition
F51.4	Sleep terrors [night terrors]
F51.3	Sleepwalking [somnambulism]
F51.5	Nightmare disorder
F51.8	Other sleep disorders not due to a substance or known physiological condition
F51.8	Other sleep disorders not due to a substance or known physiological condition
G47.01	Insomnia due to medical condition
G47.01	Insomnia due to medical condition
G47.09	Other insomnia
G47.10	Hypersomnia, unspecified
G47.11	Idiopathic hypersomnia with long sleep time
G47.13	Recurrent hypersomnia
G47.14	Hypersomnia due to medical condition
G47.19	Other hypersomnia
F51.19	Other hypersomnia not due to a substance or known physiological condition
G47.30	Sleep apnea, unspecified
G47.31	Primary central sleep apnea
G47.32	High altitude periodic breathing
G47.33	Obstructive sleep apnea (adult) (pediatric)
G47.34	Idiopathic sleep related nonobstructive alveolar hypoventilation
G47.35	Congenital central alveolar hypoventilation syndrome
G47.36	Sleep related hypoventilation in conditions classified elsewhere
G47.37	Central sleep apnea in conditions classified elsewhere
G47.39	Other sleep apnea
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.21	Circadian rhythm sleep disorder, delayed sleep phase type
G47.22	Circadian rhythm sleep disorder, advanced sleep phase type
G47.23	Circadian rhythm sleep disorder, irregular sleep wake type
G47.24	Circadian rhythm sleep disorder, free running type
G47.29	Other circadian rhythm sleep disorder

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA</b>
<b>POLICY NUMBER</b>	<b>MP 1.128</b>

<b>ICD-10-CM Diagnosis Code*</b>	<b>Description</b>
G47.50	Parasomnia, unspecified
F51.02	Adjustment insomnia
G47.51	Confusional arousals
F51.03	Paradoxical insomnia
G47.52	REM sleep behavior disorder
G47.54	Parasomnia in conditions classified elsewhere
G47.59	Other parasomnia
G47.61	Periodic limb movement disorder
G47.62	Sleep related leg cramps
G47.63	Sleep related bruxism
G47.69	Other sleep related movement disorders
G47.8	Other sleep disorders
G25.3	Myoclonus
G25.81	Restless legs syndrome
G47.419	Narcolepsy without cataplexy
G47.411	Narcolepsy with cataplexy
G47.429	Narcolepsy in conditions classified elsewhere without cataplexy
G47.421	Narcolepsy in conditions classified elsewhere with cataplexy
G47.9	Sleep disorder, unspecified
G47.30	Sleep apnea, unspecified
G47.00	Insomnia, unspecified
G47.14	Hypersomnia due to medical condition
G47.30	Sleep apnea, unspecified
G47.10	Hypersomnia, unspecified
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.8	Other sleep disorders
G47.30	Sleep apnea, unspecified
F51.8	Other sleep disorders not due to a substance or known physiological condition
G47.8	Other sleep disorders
R06.00	Dyspnea, unspecified
R06.89	Other abnormalities of breathing
R06.09	Other forms of dyspnea
R06.3	Periodic breathing
R06.83	Snoring
R09.01	Asphyxia

## MEDICAL POLICY



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<b>POLICY NUMBER</b>	<b>MP 1.128</b>

\*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

## X. POLICY HISTORY

<b>MP-1.128</b>	<b>CAC 7/26/11</b> Adopt BCBSA. Information related to surgical intervention for treatment of sleep apnea and upper airway resistance syndrome was extracted from MP 2.045 and this separate policy created. List of CBC medically necessary surgical interventions was deleted and only UPPP, hyoid suspension, surgical modification of tongue, maxillofacial surgery and adenotonsillectomy for pediatric patients are now listed as medically necessary to match BCBSA. Laser assisted tonsillectomy when the laser is used to vaporize the surface of the tonsils is no longer included on the list of investigational procedures. Otherwise investigational list is essentially the same with minor wording changes. Added statement indicating “all other minimally invasive surgical procedures not described above” are listed as investigational. Information regarding upper airway resistance syndrome remains in the policy.
	<b>CAC 1/29/13</b> Consensus review. References updated; no changes to the policy statements. FEP variation revised to refer to the FEP medical policy manual.

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA</b>
<b>POLICY NUMBER</b>	<b>MP 1.128</b>

<b>05/29/2013</b> -Administrative code review.
<b>7/26/13</b> Admin coding review complete—rsb
<b>CAC 9/24/13</b> Consensus. Policy guidelines and rationale section added.
<b>07/03/2014</b> - Admin coding review-sb

*Health care benefit programs issued or administered by Capital BlueCross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the BlueCross BlueShield Association. Communications issued by Capital BlueCross in its capacity as administrator of programs and provider relations for all companies.*