Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Policy # 00329
Original Effective Date: 07/27/2012
Current Effective Date: 02/15/2017

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

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

Note: Actigraphy is addressed separately in medical policy 00330.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

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

Based on review of available data, the Company may consider palatopharyngoplasty (e.g., uvulopalatopharyngoplasty (UPPP), uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) for the treatment of clinically significant obstructive sleep apnea syndrome (OSA) in appropriately selected adult patients who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA) to be eligible for coverage.

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

Patient Selection Criteria for OSA in Adult Patients
Clinically significant obstructive sleep apnea syndrome (OSA) is defined as those patients who meet the following criteria:

- Apnea/hypopnea index (AHI) of at least 15 events per hour; or
- Apnea/hypopnea index (AHI) of at least 5 events per hour in a patient with excessive daytime sleepiness, unexplained hypertension, ischemic heart disease, or history of stroke.

Based on review of available data, the Company may consider adenotonsillectomy in pediatric patients with clinically significant obstructive sleep apnea syndrome (OSA) and hypertrophic tonsils to be eligible for coverage.
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Patient Selection Criteria for OSA in Pediatric Patients
Clinically significant obstructive sleep apnea syndrome (OSA) is defined as those patients who meet the following criteria:

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

When Services Are Considered Not Medically Necessary
Based on review on available data, the Company considers surgical treatment of obstructive sleep apnea syndrome (OSA) that does not meet the criteria above to be not medically necessary.

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

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

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

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

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

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

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

Background/Overview
Obstructive sleep apnea syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. OSA is associated with a heterogeneous group of anatomic variants producing obstruction. In patients with OSA, the normal pharyngeal narrowing may be accentuated by anatomic factors, such as a short, fat “bull” neck, elongated palate and uvula, and large tonsillar pillars with redundant lateral pharyngeal wall mucosa. In addition, OSA is associated with obesity. Obstructive sleep apnea may also be associated with a variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. Obstruction anywhere along 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, ie, cars, trucks, heavy equipment. Obstructive sleep apnea in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

Diagnosis
The 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 (SaO₂) of at least 3% to 5%. Respiratory event-related arousals (RERAs) are scored if there is a sequence of breaths lasting at least 10 seconds characterized by increasing respiratory effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea or hypopnea. The AHI is defined as the total number of apneas and hypopneas per hour of sleep. The RDI may be defined as the number of apneas, hypopneas, and RERAs per hour of sleep. When sleep onset and offset are unknown (eg, in home sleep studies), the RDI may be calculated...
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based on the number of apneas and hypopneas per hour of recording time. Obstructive sleep apnea is considered to be clinically significant when an adult patient has an AHI of 5 or more and symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke. An AHI of 15 to 30 is typically considered moderate OSA, while an AHI of 30 or more is considered severe OSA. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds. Hypopneas are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in SaO2 or an associated arousal. In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 or more is considered severe.

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

Treatment
Nonsurgical treatment for OSA or UARS includes CPAP or orthodontic repositioning devices. Traditional surgeries for OSA or UARS include UPPP and a variety of maxillofacial surgeries such as MMA. UPPP involves surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. The amount of tissue removed is individualized for each patient as determined by the potential space and width of the tonsillar pillar mucosa between the 2 palatal arches. The UPPP enlarges the oropharynx but cannot correct obstructions in the hypopharynx. Thus, patients who fail UPPP may be candidates for additional procedures, depending on the site of obstruction. Additional procedures include hyoid suspensions, maxillary and mandibular osteotomies, or modification of the tongue. Drug-induced sleep 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 are being evaluated for OSA in adults.

Laser-assisted Uvulopalatoplasty
Laser-assisted uvulopalatoplasty is an outpatient procedure that has been proposed as a treatment of snoring with or without associated OSA. In this procedure, superficial palatal tissues are sequentially reshaped using a carbon dioxide laser. The extent of the surgery is typically different than standard UPPP, because only part of the uvula and associated soft-palate tissues are reshaped. The procedure 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
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A 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. 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.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

In 1998 the Somnoplasty™ device has been cleared for marketing by the FDA through the 510(k) for RFA of palatal tissues for simple snoring and for the base of the tongue for OSA. FDA product code: GEI.

In 1999 AIRvance™ (Medtronic; formally the Repose™ Bone Screw System from Influence) was cleared for marketing through the 510(k) process 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 in 2011 though the 510(k) process. FDA determined that this device was substantially equivalent to the PRELUDE III Tongue Suspension System (Siesta Medical) as a predicate device. FDA product codes: LRK, ORY.
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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).” U.S. Food and Drug Administration product code: LRK.

In 2014, the Inspire® II Upper Airway Stimulation System (Inspire Medical Systems) received FDA approval through the premarket approval process. In 2011, Apnex Medical received FDA approval to conduct a randomized investigational device exemption 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®.

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

Rationale/Source  
This policy was originally based on Technology Evaluation Center (TEC) Assessments on the surgical management and radiofrequency volumetric tissue reduction of OSA and updated with periodic literature reviews. The most recent literature update was performed through October 4, 2016.

Laser-Assisted Uvulopalatoplasty  
Ferguson et al reported on a randomized controlled trial (RCT) that allocated 45 subjects with mild-to-moderate sleep apnea (defined as an AHI ranging between 10 and 27 events per hour) to either LAUP or no treatment. The LAUP procedure was repeated at 1- to 2-month intervals until either the snoring was significantly reduced, no more tissue could safely be removed, or the patient refused further procedures. The primary outcome measurement was the reduction in AHI in the LAUP group versus the control group. An AHI of less than 10 was considered successful treatment. In the treatment group, 24% were considered treatment successes and 76% were failures. In the control group (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 Respiratory Disturbance Index (RDI) or AHI and a postoperative RDI or AHI of less than 20 events per hour. 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%. Success rates of 61.1% each were 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). RCTs are needed to determine whether tongue suspension alone or added to UPPP improves the net health outcome compared with UPPP alone.

Radiofrequency Volumetric Reduction of Palatal Tissues and Base of Tongue
The analysis of radiofrequency volumetric tissue reduction (ie, Somnoplasty) was originally based on a 2000 TEC Assessment that evaluated 4 primary studies on palatal RFA and 1 study on tongue base RFA. All studies were nonrandomized. In 2008, Farrar et al published a meta-analysis of RFA for the treatment of OSA in patients with an RDI of 5 or more events per hour. Sixteen studies met the inclusion criteria; 3 were randomized and 13 were nonrandomized. Six studies treated both the base of the tongue and the soft palate, 2 treated the soft palate only, and 8 ablated the base of the tongue only. 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) score was less than 10. Meta-analysis indicated a 31% reduction in both ESS and RDI. Only 2 of the studies provided 2-year follow-up, with a 32% reduction in ESS score and a 45% reduction in RDI.

A single-blinded RCT of single-stage radiofrequency surgery of the soft palate was reported by Back et al in 2009. Thirty-two patients with mild OSA and excessive daytime sleepiness were randomized to a single session of RFA or sham ablation. There was no difference between groups for baseline to posttreatment changes in ESS score (3-point improvement in ESS scores 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.

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 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.
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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 months' follow-up, the average AHI increased in both groups from a baseline of about 17, although the increase was greater in the placebo group (8.9 vs 2.9, respectively). A reduction in AHI by at least 50% or to below 20 was more common in the implant group (26% vs 10%, respectively; p=0.05). Improvement in ESS did not differ from that of sham (p=0.62). Partial implant extrusion occurred in 2 patients (4%).

Friedman et al reported an industry-sponsored randomized double-blind, sham-controlled trial of palatal implants in 62 patients with symptoms of OSA. Other inclusion criteria included: Friedman tongue position I, II, or III; diagnosis of mild to moderate OSA (AHI >5 and <40) on baseline PSG; a soft palate of 2 cm or more but less than 3.5 cm; and BMI less than 32 kg/m². AHI at baseline was 23.8 events per hour in the implant group and 20.1 in controls. Seven patients did not return for repeat PSG and were considered treatment failures in the intent-to-treat (ITT) analysis. At 3-month follow-up, the AHI improved to 15.9 events per hour in the implant group but did not change significantly in the controls (21.0). The ESS improved from 12.7 to 10.2 in the implant group and did not change significantly in the controls (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 SaO₂ improved from 82.8% to 88.3%. These measures did not improve significantly in the control group, and there was no significant difference in outcomes between the implant and control groups in this small trial. The ESS did not improve significantly in either group.

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

Neruntarat reported a case series with a minimum of 24-month follow-up. This study included 92 patients with mild to moderate OSA (AHI <30 with daytime sleepiness or disturbed sleep) who had received palatal implants after failed medical management. At baseline, the mean AHI was 21.7 events per hour, and the lowest SaO₂ was 87.4%. At mean 28.9-month follow-up, the AHI had decreased to 10.8, and the lowest
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SaO₂ improved to 89.2%. Sleep efficiency improved from 80.6% to 87.2%, and the ESS score improved from a mean of 12.3 to 7.9. Implant extrusion occurred in 7 patients (7.6%), and palatal abscess occurred in 1 patient (1.1%).

Section Summary
The literature on palatal implants consists of 3 RCTs and additional case series with medium-term follow-up. Evidence from sham-controlled trials shows a statistically significant but modest reduction in AHI and improvement in lowest SaO₂ 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 an industry-sponsored multicenter single-arm study (n=126) of the Inspire Upper Airway Stimulation system. Eighteen-month outcomes were reported in 2015 and 2- and 3-year outcomes were reported in 2016. Patients were included if their AHI from the screening PSG was at least 20 and no more than 50 events per hour, their BMI was 32 kg/m² or less, they had failed conservative therapy, and drug-induced sleep endoscopy showed a favorable pattern of palatal collapse (not complete concentric retropalatal obstruction). Stimulation parameters of the devices were titrated in the sleep laboratory with full PSG. At 12 months after implantation, 66% of 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 (ODI) score of 25% or more. The median AHI decreased from 29.3 to 9.0 events per hour. Mean ESS score decreased from 11.6 to 7.0q1.

The first 46 patients who responded to therapy were then randomized to either continued therapy or withdrawal from therapy for 1 week. 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 explantation 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 (see Table 1) 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 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% (eg, AHI from 44 to 20, ODI from 21 to 10), and the ESS improved from 12 to 7. All of the included studies described minor complications such as tongue weakness, tongue soreness, pain/swelling at the neck incision, fever, and lack of tongue response to stimulation. Of the 200 patients, 9 (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.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<td>ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3)</td>
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<td>Unpublished</td>
<td>Pivotal Study of the Apnex Medical™ Hypoglossal Nerve Stimulation (HGNS) System to Treat Obstructive Sleep Apnea</td>
<td>132</td>
<td>Aug 2013 (terminated)</td>
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NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.
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Summary
For individuals who have 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 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 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.

Practice Guidelines and Position Statements
American Academy of Sleep Medicine
The 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 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 was recommended as an “option” for patients with mild-to-moderate OSA who cannot tolerate or are unwilling to adhere to CPAP, or in whom oral appliances have been found ineffective or undesirable. Palatal implants were recommended as an “option” for patients with mild OSA who failed medical therapy. Laser-assisted uvulopalatoplasty was not recommended as a routine treatment for OSA (standard). The practice parameters recommended as “standard” the need to determine 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 were also not clear from the available literature.

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

In its 2012 position statement on UPPP, AAO-HNS concluded that UPPP is a valid treatment of OSA. Simultaneous and serial surgical procedures were considered medically necessary and effective for patients with mild-to-severe OSA. Another 2012 position statement recommended tongue suspension as effective when considered as part of a comprehensive approach in the medical and surgical management of adults with mild OSA and in adults with moderate and severe OSA who have evidence of tongue base or associated hypopharyngeal obstruction. AAO-HNS noted 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 PSG for sleep-disordered breathing before tonsillectomy in children. In addition to recommendations for PSG, AAO-HNS 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 ≥10, oxygen saturation nadir <80% or both).

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

References
2. 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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Policy History

Original Effective Date:    07/27/2012
Current Effective Date:    02/15/2017
06/28/2012    Medical Policy Committee review
07/27/2012    Medical Policy Implementation Committee approval. New policy.
12/06/2012    Medical Policy Committee review
12/19/2012    Medical Policy Implementation Committee. Coverage eligibility statement amended to clarify that the denial is not medically necessary when criteria are not met.
06/27/2013    Medical Policy Committee review
07/17/2013    Medical Policy Implementation Committee. No change to coverage.
07/10/2014    Medical Policy Committee review
07/16/2014    Medical Policy Implementation Committee approval. Changed the language throughout the “May Be Eligible for Coverage” section from “not responded to or do tolerate nasal continuous positive airway pressure (CPAP)” to “failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA)”. Added that “surgical treatment of obstructive sleep apnea syndrome (OSA) that does not meet the criteria above” to the “Not Medically Necessary” section. Added investigational statement for hypoglossal nerve stimulation.
06/25/2015    Medical Policy Committee review
07/15/2015    Medical Policy Implementation Committee. No change to coverage.
06/30/2016    Medical Policy Committee review
07/20/2016    Medical Policy Implementation Committee. No change to coverage.
01/01/2017    Coding update: Removing ICD-9 Diagnosis Codes
02/02/2017    Medical Policy Committee review
02/15/2017    Medical Policy Implementation Committee. Updated rationale and references. Coverage statement revised to include variants of palatopharyngoplasty. RDI removed from criteria for clinically significant OSA. Updated rationale and references.

Next Scheduled Review Date:    02/2018

Coding

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Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association TEC or other nonaffiliated technology evaluation center(s);  
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or  
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:  
A. In accordance with nationally accepted standards of medical practice;  
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and  
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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