



# Louisiana

## Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

**Policy #** 00329

**Original Effective Date:** 07/27/2012

**Current Effective Date:** 02/21/2018

*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 OSA syndrome and objective documentation of hypopharyngeal obstruction who have failed an adequate trial of CPAP or failed an adequate trial of an OA to be **eligible for coverage**.

### Patient Selection Criteria for OSA in Adult Patients

Clinically significant OSA syndrome is defined as those patients who meet the following criteria:

- Apnea/hypopnea index (AHI) of at least 15 events per hour; or
- 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 OSA syndrome and hypertrophic tonsils to be **eligible for coverage**.

### Patient Selection Criteria for OSA in Pediatric Patients

Clinically significant OSA syndrome is defined as those patients who meet the following criteria:

- AHI of at least 5 events per hour; or

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- 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 OSA syndrome 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 OSA syndrome 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 OSA syndrome 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
- LAUP or radiofrequency volumetric tissue reduction of the palatal tissues; and
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation (CAPSO), 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 OSA syndrome to be **investigational**.\*

#### *Notes:*

*CPAP is the preferred first-line treatment for most patients.*

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

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### **Background/Overview**

#### **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. 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. OSA may also be associated with 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 impair daytime activity; for example, adults with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles (i.e., cars, trucks, heavy equipment). OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems; e.g., 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 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 considered to be clinically significant (see medical policy 00328). The criterion standard diagnostic test for sleep disorders is polysomnography (PSG), 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 the ongoing ventilatory effort. Obstructive hypopnea is a 30% or greater reduction of air exchange with an associated fall in oxygen saturation of at least 3% or 4%. Respiratory event-related arousals (RERAs) are scored if there is a sequence of breaths lasting at least 10 seconds characterized by increasing respiratory effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea or hypopnea. The AHI measures the total number of apneas and hypopneas per hour of sleep. The Respiratory Disturbance Index (RDI) measures the number of apneas, hypopneas, and RERAs per hour of sleep. When sleep onset and offset are unknown (e.g., in-home sleep studies), the RDI may be calculated based on the number of apneas and hypopneas per hour of recording time. OSA is considered to be clinically significant when an adult has an AHI of 5 or more, in addition to symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, 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

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rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds. Hypopneas are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or an associated arousal. In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 or more is considered severe.

A condition related to OSA has been termed UARS. UARS is characterized by a partial collapse of the airway resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha electrocardiogram 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 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.

### **Nonsurgical Treatments**

Nonsurgical treatment for OSA or UARS includes CPAP or orthodontic repositioning devices (see medical policy 00328 for a discussion).

### **Surgical Treatments**

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. 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***

LAUP is an outpatient procedure proposed as a treatment of snoring with or without associated OSA. In this procedure, superficial palatal tissues are sequentially reshaped using a carbon dioxide laser. The extent of the surgery is typically different from standard UPPP because only part of the uvula and associated soft palate tissues are reshaped. The procedure 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 so 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.

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

In this procedure, the base of the tongue is suspended with a suture that is passed through the tongue and 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 Base of 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 Procedures***

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

### ***Hypoglossal Nerve Stimulation***

Stimulation of the hypoglossal nerve contracts the genioglossus muscle, the largest upper airway dilator muscle. This causes tongue protrusion and stiffening of the anterior pharyngeal wall, potentially decreasing 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 PSG and can be adjusted by the patient during home use. This stimulation system is turned on only during sleep periods.

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

### **U.S. Food and Drug Administration (FDA)**

In 1998, the Somnoplasty<sup>®‡</sup> System was cleared for marketing by the U.S. FDA through the 510(k) process for RFA of palatal tissues for simple snoring and for the base of the tongue for OSA. FDA product code: GEI.

In 1999, AIRvance<sup>®‡</sup> (Medtronic, Minneapolis, MN; formerly the Repose<sup>™‡</sup> Bone Screw System from Influence) was cleared for marketing by FDA 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. In 2011, the Encore<sup>™‡</sup> Tongue Suspension System (Siesta Medical, Los Gatos, CA) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to the PRELUDE III Tongue Suspension System (Siesta Medical). FDA product codes: LRK, ORY.

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The Pillar<sup>®†</sup> Palatal Implant System (Restore Medical, St. Paul, MN [since acquired by Medtronic]), an implantable device, was cleared for marketing by FDA through the 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." FDA product code: LRK.

In 2014, the *Inspire<sup>®†</sup> II Upper Airway Stimulation System* (Inspire Medical Systems) was approved by FDA through the premarket approval process. In 2011, Apnex Medical (Roseville, MN) received FDA approval to conduct a randomized investigational device exemption trial for the Hypoglossal Nerve Stimulation (HGNS<sup>®†</sup>) System. The trial was terminated, and Apnex Medical has ceased operations. In 2014, ImThera Medical (San Diego, CA) received FDA approval to conduct an investigational device exemption trial with the *aura6000<sup>®†</sup>*.

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

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

### Rationale/Source

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

### LASER-ASSISTED UVULOPALATOPLASTY

Ferguson et al (2003) reported on an 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 vs 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 could be effective in some patients, but the reduction in AHI and the level of symptomatic improvement were minor overall.

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### **TONGUE BASE SUSPENSION**

In 2014, Handler et al reported on a systematic review of tongue suspension vs hypopharyngeal surgery for the treatment of OSA. Reviewers included 27 studies reporting on 4 separate procedures: tongue suspension alone, tongue suspension plus UPPP, genioglossus advancement plus UPPP, and genioglossus advancement plus hyoid suspension (GAHM) plus UPPP. Successful treatment was defined as a 50% decrease in the 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 genioglossus advancement plus UPPP (7 studies, 151 patients) and for GAHM plus UPPP (12 studies, 467 patients). The adverse events of tongue suspension appear to be milder than genioglossus advancement 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 (i.e., Somnoplasty) was originally based on a 2000 TEC Assessment that evaluated 4 primary studies on palatal RFA and a 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, two treated the soft palate only, and eight 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 randomized trial. The meta-analysis was limited by the inclusion of uncontrolled studies. An RCT of single-stage RFA found no difference in outcomes compared with sham treatment.

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### **PALATAL STIFFENING PROCEDURES**

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

There is limited evidence on CAPSO in patients with clinically significant OSA; most studies of CAPSO have focused on patients with simple snoring (AHI <5 events per hour) or mild sleep apnea (AHI <15 events per hour). 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%. The mean AHI improved from 25.1 to 16.6. 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 randomized to palatal implants or sham placebo. Patients with a body mass index (BMI) greater than 32 kg/m<sup>2</sup> were excluded from the study. About 1000 patients were evaluated to identify the 100 study patients. At 3-month follow-up, the average AHI increased in both groups from a baseline of about 17, although the increase was greater in the placebo group (8.9 vs 2.9, respectively). A reduction in AHI by at least 50% or to below 20 was more common in the implant group (26% vs 10%, respectively; p=0.05). Improvement in ESS score did not differ from that of sham (p=0.62). Partial implant extrusion occurred in 2 (4%) patients.

Friedman et al (2008) reported an industry-sponsored randomized, double-blind, sham-controlled trial of palatal implants in 62 patients with symptoms of OSA. Selection criteria included: Friedman tongue position I, II, or III; diagnosis of mild-to-moderate OSA (AHI ≥5 and <40) on baseline PSG; a soft palate of 2 cm or more but less than 3.5 cm; and BMI less than 32 kg/m<sup>2</sup>. AHI at baseline was 23.8 events per hour in the implant group and 20.1 in controls. 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 was successful in 41.9% of implanted patients compared with 0% of controls. Two patients had partial implant extrusion.

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

Uncontrolled series have provided longer follow-up data on patients treated with palatal implants. For example, Walker et al (2006, 2007) published 90-day and 15-month follow-ups 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 (84%) patients evaluated at 90 days. Twenty-two (35%) patients 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

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# Louisiana

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improvement at the extended follow-up. Mean snoring was rated as 8 at baseline (visual analog scale) and as 4 at both 90 days and 15 months. Subjective daytime sleepiness measured by the ESS score was reduced at 90 days (11 to 7) but returned to 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 (2011) reported a case series with a minimum of the 24-month follow-up. This series included 92 patients with mild-to-moderate OSA (AHI  $\leq$ 30 events per hour 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 mean ESS score improved from 12.3 to 7.9. Implant extrusion occurred in 7 (7.6%) patients, and palatal abscess occurred in 1 (1.1%) patient.

### Section Summary: Palatal Stiffening Procedures

The literature on palatal implants consists of 3 RCTs and case series with medium-term follow-up. Evidence from sham-controlled trials has shown a statistically significant but modest reduction in AHI and improvement in lowest oxygen saturation compared with placebo, with limited effects on daytime sleepiness. Additional study is needed to determine whether there is a defined subset of patients who might benefit from this procedure. Studies with longer term follow-up are also needed to evaluate the long-term risk of implant extrusion.

### 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/m<sup>2</sup> 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. The mean ESS score decreased from 11.6 to 7.0.

The first 46 patients who responded to therapy were then randomized to continued therapy or withdrawal from therapy for 1 week. After 7 days, the mean AHI of the continued treatment group remained stable, whereas the mean AHI of the withdrawal group increased from 7.6 to 25.8 and ODI score increased from 6.0 to 23.0. 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.

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# Louisiana

## Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Policy # 00329

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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, with fewer 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 with 77% at 36 months. A normal Functional Outcomes of Sleep Questionnaire score (>17.9) was reported for 15% of patients at baseline compared with 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 HGNS System was reported in 2014. Apnex Medical terminated its 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 (total N=200 patients) assessing HGNS. No comparative trials were identified. Two series were identified on the Inspire II System and included the STAR trial (previously described). Three series were identified with the HGNS System and included the 2014 study of 31 patients previously described. One series of 13 patients who received the Aura6000 System was identified. When data were combined for meta-analysis, AHI and ODI scores improved by a little over 50% (e.g., AHI from 44 to 20 events per hour, ODI scores from 21 to 10), and ESS scores improved from 12 to 7. All selected 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 the removal of the stimulator.

### **Section Summary: Hypoglossal Nerve Stimulation**

The evidence on HGNS 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 HGNS to established surgical procedures is needed to permit conclusions on the effect of this treatment on health outcomes.

### **SUMMARY OF EVIDENCE**

For individuals who have OSA who receive laser-assisted uvulopalatoplasty, tongue base suspension, radiofrequency volumetric reduction of palatal tissues and base of tongue, palatal stiffening procedures, or HGNS, 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; further, none of these procedures has improved results on the Apnea-Hypopnea Index,

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# Louisiana

## Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Policy # 00329

Original Effective Date: 07/27/2012

Current Effective Date: 02/21/2018

which measures the severity of a person's sleep apnea, nor has it reduced excessive daytime sleepiness in adults with moderate-to-severe OSA. HGNS 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 the AHI, BMI, and favorable pattern of palatal collapse also met criteria for significant decreases in AHI or ODI. It should be noted that the role of nerve stimulation among the surgical procedures for OSA treatment is uncertain. RCTs comparing HGNS with conventional surgical procedures are needed to evaluate benefits and harms. The evidence is insufficient to determine the effects of the technology on health outcomes.

### References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome", 7.01.101, 9:2017.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Surgical management of sleep apnea. *TEC Assessments*. 1995;Volume 10:Tab 32.
3. 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.
4. 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*. Jan 1 2003;167(1):15-19. PMID 12502473
5. Handler E, Hamans E, Goldberg AN, et al. Tongue suspension: an evidence-based review and comparison to hypopharyngeal surgery for OSA. *Laryngoscope*. Jan 2014;124(1):329-336. PMID 23729234
6. Farrar J, Ryan J, Oliver E, et al. Radiofrequency ablation for the treatment of obstructive sleep apnea: a meta-analysis. *Laryngoscope*. Oct 2008;118(10):1878-1883. PMID 18806478
7. 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*. Aug 2009;119(8):1621-1627. PMID 19504550
8. Mair EA, Day RH. Cautery-assisted palatal stiffening operation. *Otolaryngol Head Neck Surg*. Apr 2000;122(4):547-556. PMID 10740176
9. Pang KP, Terris DJ. Modified cautery-assisted palatal stiffening operation: new method for treating snoring and mild obstructive sleep apnea. *Otolaryngol Head Neck Surg*. May 2007;136(5):823-826. PMID 17478223
10. 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*. Jul 2000;123(1 Pt 1):55-60. PMID 10889482
11. Steward DL, Huntley TC, Woodson BT, et al. Palate implants for obstructive sleep apnea: multi-institution, randomized, placebo-controlled study. *Otolaryngol Head Neck Surg*. Oct 2008;139(4):506-510. PMID 18922335
12. Friedman M, Schach P, Lin HC, et al. Palatal implants for the treatment of snoring and obstructive sleep apnea/hypopnea syndrome. *Otolaryngol Head Neck Surg*. Feb 2008;138(2):209-216. PMID 18241718
13. 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*. Jul 2012;269(7):1851-1856. PMID 22228439
14. Walker RP, Levine HL, Hopp ML, et al. Palatal implants: a new approach for the treatment of obstructive sleep apnea. *Otolaryngol Head Neck Surg*. Oct 2006;135(4):549-554. PMID 17011415
15. Walker RP, Levine HL, Hopp ML, et al. Extended follow-up of palatal implants for OSA treatment. *Otolaryngol Head Neck Surg*. Nov 2007;137(5):822-827. PMID 17967653
16. Neruntarat C. Long-term results of palatal implants for obstructive sleep apnea. *Eur Arch Otorhinolaryngol*. Jul 2011;268(7):1077-1080. PMID 21298386
17. Strollo PJ, Jr., Soose RJ, Maurer JT, et al. Upper-airway stimulation for obstructive sleep apnea. *N Engl J Med*. Jan 9 2014;370(2):139-149. PMID 24401051
18. Strollo PJ, Jr., Gillespie MB, Soose RJ, et al. Upper airway stimulation for obstructive sleep apnea: durability of the treatment effect at 18 months. *Sleep*. 2015;38(10):1593-1598. PMID 26158895
19. Woodson BT, Soose RJ, Gillespie MB, et al. Three-year outcomes of cranial nerve stimulation for obstructive sleep apnea: the STAR Trial. *Otolaryngol Head Neck Surg*. Jan 2016;154(1):181-188. PMID 26577774

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# Louisiana

## Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Policy # 00329

Original Effective Date: 07/27/2012

Current Effective Date: 02/21/2018

20. Soose RJ, Woodson BT, Gillespie MB, et al. Upper airway stimulation for obstructive sleep apnea: self-reported outcomes at 24 months. *J Clin Sleep Med*. Jan 2016;12(1):43-48. PMID 26235158
21. Woodson BT, Gillespie MB, Soose RJ, et al. Randomized controlled withdrawal study of upper airway stimulation on OSA: short- and long-term effect. *Otolaryngol Head Neck Surg*. Nov 2014;151(5):880-887. PMID 25205641
22. Kezirian EJ, Goding GS, Jr., Malhotra A, et al. Hypoglossal nerve stimulation improves obstructive sleep apnea: 12-month outcomes. *J Sleep Res*. Feb 2014;23(1):77-83. PMID 24033656
23. Certal VF, Zaghi S, Riaz M, et al. Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: A systematic review and meta-analysis. *Laryngoscope*. May 2015;125(5):1254-1264. PMID 25389029
24. 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*. Oct 1 2010;33(10):1408-1413. PMID 21061864
25. 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*. Oct 1 2010;33(10):1396-1407. PMID 21061863
26. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. Sep 2012;130(3):e714-755. PMID 22926176
27. American Academy of Otolaryngology-Head and Neck Surgery. 2016 Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA) <http://www.entnet.org/content/position-statement-hypoglossal-nerve-stimulation-treatment-obstructive-sleep-apnea-osa>. Accessed August 28, 2017.
28. American Academy of Otolaryngology -- Head and Neck Surgery. Position Statement: Surgical Management of Obstructive Sleep Apnea. 2014; <http://www.entnet.org/Practice/policySurgicalMgmtApnea.cfm>. Accessed September 1, 2017.
29. American Academy of Otolaryngology -- Head and Neck Surgery. Position Statement: Uvulopalatopharyngoplasty. 2012; <http://www.entnet.org/content/uvulopalatopharyngoplasty>. Accessed September 1, 2017.
30. American Academy of Otolaryngology -- Head and Neck Surgery. Position Statement: Tongue Suspension. 2016; <http://www.entnet.org/Practice/policytonguesuspension.cfm>. Accessed September 1, 2017.
31. 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*. Jul 2011;145(1 Suppl):S1-15. PMID 21676944
32. Clinical Issues Committee, American Society for Metabolic & Bariatric Surgery. Peri-operative management of obstructive sleep apnea. 2012; <https://asmb.org/resources/peri-operative-management-of-obstructive-sleep-apnea>. Accessed September 1, 2017.
33. Centers for Medicare & Medicaid Services. Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093N). 2001; [https://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=AAAAAAAEAAA&](https://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=AAAAAAAEAAA&). Accessed September 1, 2017.

### Policy History

Original Effective Date: 07/27/2012

Current Effective Date: 02/21/2018

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|------------|--|
| 06/28/2012 | Medical Policy Committee review  |
| 07/27/2012 | Medical Policy Implementation Committee approval. New policy.  |
| 12/06/2012 | Medical Policy Committee review  |
| 12/19/2012 | Medical Policy Implementation Committee. Coverage eligibility statement amended to clarify that the denial is not medically necessary when criteria are not met.   |
| 06/27/2013 | Medical Policy Committee review  |
| 07/17/2013 | Medical Policy Implementation Committee. No change to coverage.  |
| 07/10/2014 | Medical Policy Committee review  |
| 07/16/2014 | Medical Policy Implementation Committee approval. Changed the language throughout the "May Be Eligible for Coverage" section from "not responded to or do tolerate nasal continuous positive airway pressure (CPAP)" to "failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance (OA)". Added that "surgical treatment of obstructive sleep apnea syndrome (OSA) that does not meet the criteria above" to the "Not Medically Necessary" section. Added investigational statement for hypoglossal nerve stimulation. |
| 06/25/2015 | Medical Policy Committee review  |

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# Louisiana

## Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Policy # 00329

Original Effective Date: 07/27/2012

Current Effective Date: 02/21/2018

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.  
 02/01/2018 Medical Policy Committee review  
 02/21/2018 Medical Policy Implementation Committee approval. Deleted 2 sentences from the "Notes" in the coverage section regarding the use of oral appliances and the definition of the Respiratory Disturbance Index. Coverage eligibility unchanged.  
 Next Scheduled Review Date: 02/2019

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HCPCS	C9727, S2080
ICD-10 Diagnosis	G47.10, G47.30-G47.37, G47.9, R06.00, R06.09, R06.1, R06.3, R06.81, R06.83, R06.89

\*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:

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# Louisiana

## Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Policy # 00329

Original Effective Date: 07/27/2012

Current Effective Date: 02/21/2018

- 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 technology assessment program (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.

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- 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.

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