MEDICAL POLICY – 7.01.554
Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

BCBSA Ref. Policy: 7.01.101

Effective Date: June 1, 2018
Last Revised: June 1, 2018
Replaces: N/A

RELATED MEDICAL POLICIES:
11.01.524 Site of Service: Select Surgical Procedures

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Obstructive sleep apnea (OSA) is a blockage in the upper part of the airway. The blockage is usually from throat muscles collapsing, the tongue falling into the airway, or large tonsils or adenoids getting in the way of airflow. Positive airway pressure (PAP) devices are very effective in treating sleep apnea. A PAP device works by increasing air pressure in the throat to prevent it from collapsing as a person breathes. When a PAP device doesn’t work or there are certain other medical situations, surgery can be a way to treat sleep apnea. There are a number of different types of surgery, but they generally treat OSA by removing extra tissue in the throat to widen the airway. There are also a number of other surgeries or devices that are still being studied. They are not covered because there is not enough medical evidence to show they work. This policy discusses when medically necessary surgeries for OSA may be approved.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

### Site of Service for Elective Surgical Procedures

<table>
<thead>
<tr>
<th>Medically necessary sites of service:</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Off campus-outpatient hospital/medical center</td>
<td>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.</td>
</tr>
<tr>
<td>• On campus-outpatient hospital/medical center</td>
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<tr>
<td>• Ambulatory Surgical Center</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Inpatient hospital/medical center</th>
<th>Medical Necessity</th>
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<tbody>
<tr>
<td></td>
<td>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the patient has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):</td>
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<tr>
<td></td>
<td>• Anesthesia Risk</td>
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<tr>
<td></td>
<td>o ASA classification III or higher (see definition)</td>
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<tr>
<td></td>
<td>o Personal history of complication of anesthesia</td>
</tr>
<tr>
<td></td>
<td>o Documentation of alcohol dependence or history of cocaine use</td>
</tr>
<tr>
<td></td>
<td>o Prolonged surgery (&gt;3 hours)</td>
</tr>
<tr>
<td></td>
<td>• Cardiovascular Risk</td>
</tr>
<tr>
<td></td>
<td>o Uncompensated chronic heart failure (NYHA class III or IV)</td>
</tr>
<tr>
<td></td>
<td>o Recent history of myocardial infarction (MI) (&lt;3 months)</td>
</tr>
<tr>
<td></td>
<td>o Poorly controlled, resistant hypertension*</td>
</tr>
<tr>
<td></td>
<td>o Recent history of cerebrovascular accident (&lt; 3 months)</td>
</tr>
<tr>
<td></td>
<td>o Increased risk for cardiac ischemia (drug eluting stent placed &lt; 1 year or angioplasty &lt;90 days)</td>
</tr>
<tr>
<td>Site of Service for Elective Surgical Procedures</td>
<td>Medical Necessity</td>
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<tr>
<td>------------------------------------------------</td>
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</tr>
<tr>
<td>o Symptomatic cardiac arrhythmia despite medication</td>
<td></td>
</tr>
<tr>
<td>o Significant valvular heart disease</td>
<td></td>
</tr>
<tr>
<td>• Liver Risk</td>
<td></td>
</tr>
<tr>
<td>o Advance liver disease (MELD Score &gt; 8)**</td>
<td></td>
</tr>
<tr>
<td>• Pulmonary Risk</td>
<td></td>
</tr>
<tr>
<td>o Chronic obstructive pulmonary disease (COPD) (FEV1 &lt;50%)</td>
<td></td>
</tr>
<tr>
<td>o Poorly controlled asthma (FEV1 &lt;80% despite treatment)</td>
<td></td>
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<tr>
<td>o Moderate to severe obstructive sleep apnea (OSA)***</td>
<td></td>
</tr>
<tr>
<td>• Renal Risk</td>
<td></td>
</tr>
<tr>
<td>o End stage renal disease (on dialysis)</td>
<td></td>
</tr>
<tr>
<td>• Other</td>
<td></td>
</tr>
<tr>
<td>o Morbid obesity (BMI ≥ 50)</td>
<td></td>
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<tr>
<td>o Pregnancy</td>
<td></td>
</tr>
<tr>
<td>o Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria])</td>
<td></td>
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<tr>
<td>o Anticipated need for transfusion(s)</td>
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</tbody>
</table>

* 3 or more drugs to control blood pressure
*** Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30
****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)

| Inpatient hospital/medical center | This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met. |

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract limitations</td>
<td>Some health plan contracts do not have benefits to cover orthognathic surgery. Refer to member contract language for benefit determination where applicable.</td>
</tr>
<tr>
<td>Uvulopalatopharyngoplasty</td>
<td>UPPP may be considered medically necessary for the</td>
</tr>
</tbody>
</table>
### Treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>(UPPP)</td>
<td>treatment of clinically significant obstructive sleep apnea syndrome (OSA) in appropriately selected adult patients who have not responded to or do not tolerate nasal continuous positive airway pressure (CPAP).</td>
</tr>
<tr>
<td></td>
<td>Note: Clinically significant OSA is defined in the Related Information section.</td>
</tr>
<tr>
<td>Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery</td>
<td>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 and objective documentation of hypopharyngeal obstruction who have not responded to or do not tolerate CPAP.</td>
</tr>
<tr>
<td></td>
<td>Note: Clinically significant OSA is defined in the Related Information section.</td>
</tr>
<tr>
<td>Adenotonsillectomy</td>
<td>Adenotonsillectomy may be considered medically necessary in pediatric patients with clinically significant OSA and hypertrophic tonsils.</td>
</tr>
<tr>
<td></td>
<td>Note: Clinically significant OSA is defined in the Related Information section.</td>
</tr>
<tr>
<td>All interventions in the absence of documented OSA</td>
<td>All interventions, including LAUP (laser-assisted uvulopalatoplasty), 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.</td>
</tr>
</tbody>
</table>

### Treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantable hypoglossal nerve stimulators</td>
<td>Implantable hypoglossal nerve stimulators are investigational for all indications, including but not limited to the treatment of obstructive sleep apnea (OSA).</td>
</tr>
<tr>
<td>Minimally-invasive surgical procedures</td>
<td>The following minimally-invasive surgical procedures are investigational for the sole or adjunctive treatment of OSA or</td>
</tr>
</tbody>
</table>
**Treatment**  | **Investigational upper airway resistance syndrome (UARS):**
--- | ---
- Radiofrequency volumetric tissue reduction of the tongue (eg, Somnoplasty), with or without radiofrequency reduction of the palatal tissues
- Laser-assisted uvulopalatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues
- 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 (eg, Pillar Procedure)
- Tongue base suspension (eg, Airvance System, formerly the Repose™ Tongue and Hyoid Suspension System, Encore™ system)
- All other minimally-invasive surgical procedures not described above

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>0466T</td>
<td>Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0467T</td>
<td>Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>21199</td>
<td>Osteotomy, mandible, segmental; with genioglossus advancement</td>
</tr>
<tr>
<td>41512</td>
<td>Tongue base suspension, permanent suture technique</td>
</tr>
<tr>
<td>41530</td>
<td>Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session</td>
</tr>
<tr>
<td>42145</td>
<td>Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty)</td>
</tr>
<tr>
<td>42299</td>
<td>Unlisted procedure, palate, uvula</td>
</tr>
<tr>
<td>42950</td>
<td>Pharyngoplasty (plastic or reconstructive operation on pharynx)</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>64568</td>
<td>Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2080</td>
<td>Laser-assisted uvulopalatoplasty (LAUP)</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**

Continuous positive airway pressure is the preferred first-line treatment for most patients with OSA. A smaller number of patients may use oral appliances as a first-line treatment (see Related Policies).

The Apnea/Hypopnea Index is the total number events (apnea or hypopnea) per hour of recorded sleep. The Respiratory Disturbance Index 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 compared with baseline, and with at least a 4% oxygen desaturation.

**Definition of Terms**

**American Society of Anesthesiologists (ASA) Score:**

- **ASA 1** A normal healthy patient.
- **ASA 2** A patient with mild systemic disease.
- **ASA 3** A patient with severe systemic disease.
- **ASA 4** A patient with severe systemic disease that is a constant threat to life.
- **ASA 5** A moribund patient who is not expected to survive

**New York Heart Association (NYHA) Classification:**
Class I  No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs etc.

Class II  Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

Class III  Marked limitation in activity due to symptoms, even during less-than-ordinary activity, eg, walking short distances (20–100 m). Comfortable only at rest.

Class IV  Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Adults

The diagnosis of OSA in adults is confirmed by a sleep study result showing:

- The apneic/hypopneic index (AHI) is greater than or equal to 15 events per hour, including a minimum of 30 events documented per sleep study; or

- The AHI is greater than or equal to 5 events per hour and less than 15 events per hour, including a minimum of 10 events documented per sleep study, AND documentation of:
  - History of stroke; or
  - Hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg); or
  - Ischemic heart disease; or
  - Symptoms of impaired cognition, mood disorders, or insomnia; or
  - Excessive daytime sleepiness (documented by either Epworth greater than 10 or MSLT less than 6); or
  - Greater than 20 episodes of desaturation (ie, oxygen saturation of less than 85%) during a full night sleep study, or any 1 episode of oxygen desaturation (ie, oxygen saturation of less than 70%); or
  - Obesity (BMI greater than 35)

OSA severity is defined as:

- Mild for AHI ≥ 5/hr and < 15/hr.
- Moderate for AHI ≥ 15/hr and < 30/hr.
- Severe for AHI ≥ 30/hr.

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 to baseline, and with at least a 4% oxygen desaturation.

**Children**

The presentation of OSA in pediatric patients may differ from that of adults.

The diagnosis of obstructive sleep apnea in children is established by a sleep study result showing an apneic/hypopneic index (AHI) greater than 1.5. (An AHI of 1.5 is considered severe in children.)

**Upper airway resistance syndrome (UARS)**

Clinically significant upper airway resistance syndrome (UARS) is defined as greater than 10 EEG arousals per hour. The presence of abnormally negative intrathoracic pressures (ie, 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. Objective evidence of hypopharyngeal obstruction is documented by either fiberoptic endoscopy or cephalometric radiographs.

**Evidence Review**

**Description**

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. For patients who have failed
conservative therapy, established surgical approaches may be indicated. This policy addresses minimally invasive surgical procedures for the treatment of OSA. They include laser-assisted uvuloplasty, tongue base suspension, radiofrequency volumetric reduction of palatal tissues and base of tongue, palatal stiffening procedures, and hypoglossal nerve stimulation. This policy does not address conventional surgical procedures such as uvulopalatopharyngoplasty, hyoid suspension, surgical modification of the tongue, maxillofacial surgery, or adenotonsillectomy.

Background

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. OSA may also be associated with a variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. Obstruction anywhere along the upper airway can result in apnea.

The hallmark symptom of OSA is excessive daytime sleepiness, and the typical clinical sign of OSA is snoring, which can abruptly cease and be followed by gasping associated with a brief arousal from sleep. The snoring resumes when the patient falls back to sleep, and the cycle of snoring/apnea/arousal may be repeated as frequently as every minute throughout the night. Sleep fragmentation associated with the repeated arousal during sleep can lead to impairment of daytime activity. For example, adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, ie, 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.

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

Summary of Evidence

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

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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</tr>
<tr>
<td>NCT02907398a</td>
<td>Adherence and Outcome of Upper Airway Stimulation (UAS) for OSA International Registry</td>
<td>2500</td>
<td>Sep 2019</td>
</tr>
<tr>
<td>NCT02263859a</td>
<td>ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3)</td>
<td>141</td>
<td>May 2021</td>
</tr>
<tr>
<td>NCT02413970</td>
<td>Inspire® Upper Airway Stimulation System (UAS): Post-Approval Study Protocol Number 2014-001</td>
<td>127</td>
<td>Dec 2021</td>
</tr>
<tr>
<td></td>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01446601a</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>
</tr>
<tr>
<td>NCT02293746a</td>
<td>Inspire® Upper Airway Stimulation (UAS) System German Post-Market Study: CE Certificate Number 562872</td>
<td>60</td>
<td>Jan 2017 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

**Practice Guidelines and Position Statements**

*American Academy of Sleep Medicine (AASM)*

The American Academy of Sleep Medicine (AASM) published practice parameters for surgical modifications of the upper airway for obstructive sleep apnea (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 Apnea-Hypopnea Index (AHI) as the primary measure of efficacy, substantial and consistent reductions were observed following mandibular-maxillary advancement (MMA), and adverse events were uncommonly reported. Outcomes following pharyngeal surgeries were less consistent, and adverse events were more commonly reported. The review found that outcomes of studies with newer pharyngeal techniques and multilevel procedures, performed in small numbers of patients, appear promising. The practice parameters noted the lack of rigorous data evaluating surgical modifications of the upper airway, resulting in a recommendation of “option” (uncertain clinical use) for MMA, uvulopalatopharyngoplasty (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 continuous positive airway pressure (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.

The American Academy of Pediatrics (AAP)

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

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS)

The 2016 American Academy of Otolaryngology-Head and Neck Surgery position statement on hypoglossal nerve stimulation for treatment of obstructive sleep apnea (OSA) states: “...upper airway stimulation (UAS) via the hypoglossal nerve for the treatment of adult obstructive sleep apnea syndrome to be an effective second-line treatment of moderate to severe obstructive sleep apnea in patients who are intolerant or unable to achieve benefit with positive pressure therapy (PAP). Not all adult patients are candidates for UAS therapy and appropriate
polysomnographic, age, BMI and objective upper airway evaluation measures are required for proper patient selection.”

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 obstructive sleep apnea. Another 2012 position statement recommended tongue suspension as effective when considered as part of a comprehensive approach in the medical and surgical management of adult patients with mild OSA and in adult patients with moderate and severe OSA who have evidence of tongue base or associated hypopharyngeal obstruction. AAO-HNS notes that results appear to diminish in obese patients, and this technique should receive a weaker recommendation for these patients.

In 2011, AAO-HNS published clinical practice guidelines on polysomnography (PSG) for sleep-disordered breathing before tonsillectomy in children. In addition to recommendations for PSG (see Related Policies), 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 published guidelines on the perioperative management of OSA. The guideline states that OSA is strongly associated with obesity with the incidence of OSA in the morbidly obese population being reported to be between 38% and 88%. They recommend bariatric surgery be the initial treatment of choice for OSA in this population, as opposed to surgical procedures directed at the mandible or tissues of the palate.
Medicare National Coverage

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

Regulatory Status

In 1998, the Somnoplasty® device was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for radiofrequency ablation of palatal tissues for simple snoring and for the base of the tongue for obstructive sleep apnea (OSA). FDA product code: GEI.

In 1999, AIRvance® (Medtronic; formerly the Repose™ Bone Screw System from Influence) was cleared for marketing by the 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™ Tongue Suspension System (Siesta Medical) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to the PRELUDE III Tongue Suspension System (Siesta Medical). FDA product codes: LRK, ORY.

The Pillar® Palatal Implant System (Restore Medical, St. Paul, MN, acquired by Medtronic, Minneapolis, MN), an implantable device, was cleared for marketing by the 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 (obstructive sleep apnea).” FDA product code: LRK.

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

References


## History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/14/14</td>
<td>New PR policy replacing 7.01.101. Medically necessary criteria for OSA diagnosis expanded to include a threshold of an AHI of 15-30 events as a specific criterion. When the AHI is 5-15, an additional requirement of documentation to evidence: stroke, hypertension, ischemic heart disease; or, symptoms of impaired cognition/mood disorder/insomnia; or, Epworth sleep scale greater than 10 or MSLT less than 6 to evidence daytime sleepiness; or, more than 20 episodes of desaturation; or obesity (BMI over 35). When the AHI is greater than 30, the patient must be able to tolerate PAP or it must be contraindicated. Criteria for children updated to an apneic/hypopneic index (AHI) greater than 1.5. ICD-9 and ICD-10 procedure and diagnosis codes removed; they are not utilized in adjudication. Policy effective subsequent to 2.01.532 effective October 23, 2014. Added investigational policy statement for implantable hypoglossal nerve stimulators.</td>
</tr>
<tr>
<td>10/23/14</td>
<td>Reissue policy as updates are now effective; reference to previous version removed.</td>
</tr>
<tr>
<td>06/17/15</td>
<td>Annual Review. No change to policy statements. Informational CPT codes removed; these are not reviewed.</td>
</tr>
<tr>
<td>02/09/16</td>
<td>Annual Review. Policy updated with literature review through January, 2016; reference 31 added; policy statements unchanged.</td>
</tr>
<tr>
<td>03/01/17</td>
<td>Annual Review, approved February 14, 2017. Policy updated with literature review through October 4, 2016; references 17-20 added. Coding update; added codes, including new CPT codes effective 1/1/17. No change to policy statements.</td>
</tr>
<tr>
<td>03/30/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Removed Related Policies 1.01.524, 2.01.503, and 2.01.532 as they were archived.</td>
</tr>
<tr>
<td>03/01/18</td>
<td>Interim Review, approved February 27, 2018. Note added that this policy has been revised. Added Surgery Site of Service criteria, which becomes effective June 1, 2018.</td>
</tr>
<tr>
<td>06/01/18</td>
<td>Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.</td>
</tr>
</tbody>
</table>
**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Oromoo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtan ladann. Avi sila a kapab genyèn enfòmasyon enpòtan kònsènan aplikasyon w lan oswa kònsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyèn dat ki enpòtan nan avi sila a. Ou ka gen pou pran kòk akson avan senten dat limit pou ka kente kouvèti asirans sante w la osa pou yo ka ede w avèk desps yo. Se dwa w pou resewa enfòmasyon sa a ak asisants nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):

Illoko (Ilocano):
Daytoy a Pakdaara ket nagloan iti Napategy nga Impormasion. Daytoy a pakdaara mabalina nga adda ket nagloan iti napategy nga impormasion maijanggep iti aplikasyonu yenyo coverage babaen iti Premera Blue Cross. Daytoy ket mabalina dagiti importante a pelsa iti daytoy a pakdaara. Mabalina nga adda rumbeng nga aramideny nga adda sakkay dagiti partikular a naitiding nga adda aldaw tapno mapagtalaineydo ti coverage ti salun-ayno yenyo tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong ti bukodyo a pagasasa nga awan ti bayadanyo. Tumawagi ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Health insurance or premium support must be maintained to the specific date. This notice may contain important dates that may affect your health insurance or premium support. Please confirm the important dates mentioned in this notification. 800-722-1471 (TTY: 800-842-5357) for assistance.

Japanese (Japanese):
この通知には重要な情報が含まれています。Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれている場合があります。この通知には記載されている可能性がある重要な日目をご確認ください。健康保険や送料サポートを維持するには、特定の期末までに行動を取らなければなりません。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

Korean (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 커버리지에 관한 정보를 포함하고 있는 것입니다. 본 통지서에는 특별히 없는 날짜들이 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 이탈하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하는 이러한 정보와 관련된 귀하의 언어와 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)으로 전화하십시오。

Lao (Lao):
ຄົນທ່ານຍັງສາມາດຮັບຂໍ້ມູນນີ້ໄດ້ຮັບຕາມກໍ້ມູນນົດການໃຊ້ຄໍ້ມູນຂອງທ່ານໂດຍບໍ່អສຍຄ່າ

Russian (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Spanish (Spanish):
Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Vietnamese (Vietnamese):
Thông báo này cung cấp thông tin quan trọng. Thông báo này có thể thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện các thao tác đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình phải. Xin gọi số 800-722-1471 (TTY: 800-842-5357)