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.
We will review for medical necessity these elective surgical procedures.

**The surgical procedure subject to medical necessity review for site of service addressed in this policy is limited to:**

- **Uvulopalatopharyngoplasty (UPPP)**

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.

<table>
<thead>
<tr>
<th>Site of Service for Elective Surgical Procedures</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medically necessary sites of service:</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>- Off campus-outpatient hospital/medical center</td>
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<tr>
<td>- On campus-outpatient hospital/medical center</td>
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<tr>
<td>- Ambulatory Surgical Center</td>
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<tr>
<td>Inpatient hospital/medical center</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>
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<tr>
<td>- Anesthesia Risk</td>
<td></td>
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<tr>
<td>o ASA classification III or higher (see definition)</td>
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<tr>
<td>o Personal history of complication of anesthesia</td>
<td></td>
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<tr>
<td>o Documentation of alcohol dependence or history of cocaine use</td>
<td></td>
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<tr>
<td>o Prolonged surgery (&gt;3 hours)</td>
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<tr>
<td>- Cardiovascular Risk</td>
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<tr>
<td>Site of Service for Elective Surgical Procedures</td>
<td>Medical Necessity</td>
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<td>-----------------------------------------------</td>
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<tr>
<td></td>
<td>- Uncompensated chronic heart failure (<strong>NYHA class</strong> III or IV)</td>
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<tr>
<td></td>
<td>- Recent history of myocardial infarction (MI) (&lt;3 months)</td>
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<tr>
<td></td>
<td>- Poorly controlled, resistant hypertension*</td>
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<tr>
<td></td>
<td>- Recent history of cerebrovascular accident (&lt; 3 months)</td>
</tr>
<tr>
<td></td>
<td>- Increased risk for cardiac ischemia (drug eluting stent placed &lt; 1 year or angioplasty &lt;90 days)</td>
</tr>
<tr>
<td></td>
<td>- Symptomatic cardiac arrhythmia despite medication</td>
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<tr>
<td></td>
<td>- Significant valvular heart disease</td>
</tr>
<tr>
<td>Liver Risk</td>
<td>- Advance liver disease (MELD Score &gt; 8)**</td>
</tr>
<tr>
<td>Pulmonary Risk</td>
<td>- Chronic obstructive pulmonary disease (COPD) (FEV1 &lt;50%)</td>
</tr>
<tr>
<td></td>
<td>- Poorly controlled asthma (FEV1 &lt;80% despite treatment)</td>
</tr>
<tr>
<td></td>
<td>- Moderate to severe obstructive sleep apnea (OSA)***</td>
</tr>
<tr>
<td>Renal Risk</td>
<td>- End stage renal disease (on dialysis)</td>
</tr>
<tr>
<td>Other</td>
<td>- Morbid obesity (BMI ≥ 50)</td>
</tr>
<tr>
<td></td>
<td>- Pregnancy</td>
</tr>
<tr>
<td></td>
<td>- Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria])</td>
</tr>
<tr>
<td></td>
<td>- Anticipated need for transfusion(s)</td>
</tr>
</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)

<p>| 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. |</p>
<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contract limitations</strong></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><strong>Uvulopalatopharyngoplasty (UPPP)</strong></td>
<td>UPPP may be considered medically necessary for the 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). Note: Clinically significant OSA is defined in the Related Information section.</td>
</tr>
<tr>
<td><strong>Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery</strong></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. Note: Clinically significant OSA is defined in the Related Information section.</td>
</tr>
<tr>
<td><strong>Adenotonsillectomy</strong></td>
<td>Adenotonsillectomy may be considered medically necessary in pediatric patients with clinically significant OSA and hypertrophic tonsils.                                                                                             Note: Clinically significant OSA is defined in the Related Information section.</td>
</tr>
</tbody>
</table>
| **Hypoglossal nerve stimulation**                                        | Hypoglossal nerve stimulation may be considered medically necessary in adults with OSA under the following conditions:  
  • Age ≥ 22 years; **and**  
  • AHI ≥ 20 with less than 25% central apneas; **and**  
  • CPAP failure (residual AHI ≥ 20 or inability to tolerate CPAP ≥ 4hrs per night for ≥ 5 nights per week); **and**  
  • Body mass index (BMI) ≤ 32 kg/m²; **and**  
  • Non-concentric retropalatal obstruction on drug induced sleep |
### Treatment

<table>
<thead>
<tr>
<th>Medical Necessity</th>
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</thead>
<tbody>
<tr>
<td>endoscopy (see Related Information)</td>
</tr>
</tbody>
</table>

**Hypoglossal nerve stimulation may be considered medically necessary in adolescents or young adults with Down syndrome and OSA under the following conditions:**

- Age 10 to 21 years; and
- AH1>10 and <50 with less than 25% central apneas after prior adenotonsillectomy; and
- Have either a tracheotomy or be ineffectively treated with CPAP due to discomfort, undesirable side effects, persistent symptoms despite compliant use; and
- Body mass index (BMI) ≤ 95th percentile for age; and
- Non-concentric retropalatal obstruction on drug induced sleep endoscopy (See Related Information)

**Implantable hypoglossal nerve stimulators are investigational for all indications, other than what is listed above.**

### All interventions in the absence of documented OSA

<table>
<thead>
<tr>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<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>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following minimally-invasive surgical procedures are investigational for the sole or adjunctive treatment of OSA or upper airway resistance syndrome (UARS):</td>
</tr>
<tr>
<td>- Laser-assisted uvulopalatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues</td>
</tr>
<tr>
<td>- 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® Palatal Implant)</td>
</tr>
</tbody>
</table>
## Treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiofrequency volumetric tissue reduction of the tongue (eg, Somnoplasty®), with or without radiofrequency reduction of the palatal tissues</td>
<td></td>
</tr>
<tr>
<td>Tongue base suspension (eg, Airvance® System, formerly the Repose™ Tongue and Hyoid Suspension System, Encore™ system)</td>
<td></td>
</tr>
<tr>
<td>All other minimally-invasive surgical procedures not described above</td>
<td></td>
</tr>
</tbody>
</table>

## Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- **Uvulopalatopharyngoplasty (UPPP):**
  - Documented clinically significant obstructive sleep apnea (OSA) with apnea hypopnea index (AHI)
  - Documentation that patient has failed or does not tolerate nasal continuous positive airway pressure (CPAP)

- **Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery:**
  - Documented clinically significant OSA with apnea hypopnea index (AHI)
  - Objective documentation of hypopharyngeal obstruction and that the patient has failed or does not tolerate nasal continuous positive airway pressure (CPAP)

- **Adenotonsillectomy:**
  - Documented OSA with apnea hypopnea index (AHI)
  - Physical exam shows enlarged tonsils

## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</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>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>--------------------------------------------------------------------------------------------------------</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>64568</td>
<td>Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</td>
</tr>
</tbody>
</table>

**HCPCS**

<table>
<thead>
<tr>
<th>Code</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. 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.

The hypoglossal nerve (cranial nerve XII) innervates the genioglossus muscle. Stimulation of the nerve causes anterior movement and stiffening of the tongue and dilation of the pharynx.
Hypoglossal nerve stimulation reduces airway collapsibility and alleviates obstruction at both the level of the soft palate and tongue base.

Drug-induced sleep endoscopy (DISE) replicates sleep with an infusion of propofol. DISE will suggest either a flat, anterior-posterior collapse or complete circumferential oropharyngeal collapse. Concentric collapse decreases the success of hypoglossal nerve stimulation and is an exclusion criterion from the Food and Drug Administration.

A hypoglossal nerve stimulator system consists of 3 implanted components: a pulse generator, a respiratory-sensing lead senses breathing patterns, and a stimulation lead surgically placed on the hypoglossal nerve delivers mild stimulation to maintain airway patency during sleep drawing the tongue forward to improve airway obstruction. All are controlled with a handheld remote turned on at the time of sleep and turned off upon awakening.

Source: Hayes Directory, Medical Technology Directory. Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea, October 30, 2018
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, eg, 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.)

**Continuous Positive Airway Pressure (CPAP)**

Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or Bi-level (Bi-PAP). CPAP is a more familiar abbreviation and will refer to all types of PAP devices.

**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.
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 (HNS).

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. 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 (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.

Clinical Context and Therapy Purpose

OSA is associated with a heterogeneous group of anatomic variants producing obstruction. 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 severity and type of obstruction may be described with the Friedman staging system.³

Nonsurgical treatment for OSA or upper airway resistance syndrome includes continuous positive airway pressure (CPAP) or mandibular repositioning devices. Patients who fail conservative therapy may be evaluated for surgical treatment of OSA.

Traditional surgeries for OSA or upper airway resistance syndrome include uvulopalatopharyngoplasty (UPPP) and a variety of maxillofacial surgeries such as mandibular-maxillary advancement. 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. Patients who have minimal hypoglossal obstruction have greater success with UPPP. 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 (LAUP) is proposed as a treatment of snoring with or without associated OSA. LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, which raises its own issues of safety and, in particular, effectiveness.

**Radiofrequency Volumetric Reduction of Palatal Tissues and Base of Tongue**

Radiofrequency (RF) is used to produce thermal lesions within the tissues rather than using a laser to ablate the tissue surface. 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 cautery-assisted palatal stiffening operation (CAPSO). Snoreplasty and CAPSO are intended for snoring, and are not discussed here. Palatal implants are cylindrically shaped devices that are implanted in the soft palate.

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.

Hypoglossal Nerve Stimulation

Stimulation of the hypoglossal nerve causes tongue protrusion and stiffening of the anterior pharyngeal wall, potentially decreasing apneic events. For patients with moderate-to-severe sleep apnea who have failed or are intolerant of CPAP, the alternative would be an established surgical procedure, as described above. Clinical input indicates that HNS leads to a meaningful improvement in health outcomes in appropriately selected adult patients with a favorable pattern of non-concentric palatal collapse. The alternative treatment for this anatomical endotype is maxillo-mandibular advancement (MMA), which is associated with greater morbidity and lower patient acceptance than HNS. The improvement in AHI with HNS, as shown in the STAR trial, is similar to the improvement in AHI following MMA. Clinical input also supports that HNS results in a meaningful improvement in health outcomes in appropriately selected adolescents with OSA and Down’s syndrome who have difficulty in using CPAP.
Table 1. Minimally Invasive Surgical Interventions for Obstructive Sleep Apnea

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Devices</th>
<th>Description</th>
<th>Key Features</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser-assisted uvulopalatoplasty (LAUP)</td>
<td>Various</td>
<td>Superficial palatal tissues are sequentially reshaped over 3 to 7 sessions using a carbon dioxide laser</td>
<td>• Part of the uvula and associated soft-palate tissues are reshaped&lt;br&gt;• Does not alter tonsils or lateral pharyngeal wall tissues&lt;br&gt;• Tissue ablation can be tritiated</td>
<td>Snoring with or without OSA</td>
</tr>
<tr>
<td>RF volumetric reduction of palatal tissues and base of tongue</td>
<td>Somnoplasty</td>
<td>Radiofrequency is used to produce thermal lesions within the tissues</td>
<td>• Similar to LAUP&lt;br&gt;• Can include soft palate and base of tongue</td>
<td>Simple snoring and base of tongue OSA</td>
</tr>
<tr>
<td>Palatal Implant</td>
<td>Pillar Palatal Implant</td>
<td>Braided polyester filaments that are implanted submucosally in the soft palate</td>
<td>Up to 5 implants may be used</td>
<td>Snoring</td>
</tr>
<tr>
<td>Tongue base suspension</td>
<td>AIRvance Encore</td>
<td>A suture is passed through the tongue and fixated with a screw to the inner side of the mandible, below the tooth roots</td>
<td>The aim of the suspension is to make it less likely for the base of the tongue to prolapse during sleep</td>
<td>Snoring and/or OSA</td>
</tr>
<tr>
<td>Hypoglossal nerve stimulation (HNS)</td>
<td>Inspire II Upper Airway Stimulation</td>
<td>Stimulation of the hypoglossal nerve which contracts the tongue and some palatal tissue</td>
<td>The device includes an implanted stimulator and a sensor implanted in the ribs to detect respiration.</td>
<td>A subset of patients with moderate-to-severe OSA who have failed or cannot tolerate CPAP (see Regulatory Status section)</td>
</tr>
</tbody>
</table>

CPAP: positive airway pressure; LAUP: Laser-assisted uvulopalatoplasty; OSA: obstructive sleep apnea.
Summary of Evidence

The following conclusions are based on a review of the evidence, including, but not limited to, published evidence and clinical expert opinion, via BCBSA’s Clinical Input Process.

For individuals who have OSA who receive laser-assisted uvulopalatoplasty (LAUP), the evidence includes a single randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The trial indicates reductions in snoring, but limited efficacy on the apnea/hypopnea index or symptoms in patients with mild-to-moderate OSA. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive radiofrequency (RF) volumetric reduction of palatal tissues and base of tongue the evidence includes two sham-controlled RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Single-stage RF to palatal tissues did not improve outcomes compared to sham. Multiple sessions of RF to the palate and base of tongue did not significantly (statistically or clinically) improve AHI, and the improvement in functional outcomes were not clinically significant. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive palatal stiffening procedures, the evidence includes two sham-controlled randomized trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The two RCTs differed in their inclusion criteria, with the study that excluded patients with Friedman tongue position of IV and palate of 3.5 cm or longer reporting greater improvement in AHI (45% success) and snoring (change of -4.7 on a 10 point VAS) than the second trial. Additional study is needed to corroborate results of the more successful trial and if successful, define the appropriate selection criteria. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive tongue base suspension, the evidence includes a feasibility RCT with 17 patients. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT compared tongue suspension plus UPPP to tongue advancement plus UPPP and showed success rates of 50% to 57% for both of the procedures. RCTs with a larger number of subjects are needed to determine whether tongue suspension alone or added to UPPP improves the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive hypoglossal nerve stimulation, the evidence includes two non-randomized studies with historical controls and prospective single arm studies.
Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Hypoglossal nerve stimulation has shown success rates for about two thirds of a subset of patients who met selection criteria that included AHI, body mass index, and favorable pattern of palatal collapse. These results were maintained out to 5 years in the pivotal single arm study. Clinical input supplements and informs the interpretation of the published evidence. Clinical input indicates that HNS leads to a meaningful improvement in health outcomes in appropriately selected adult patients with a favorable pattern of non-concentric palatal collapse. The alternative treatment for this anatomical endotype is maxillo-mandibular advancement (MMA), which is associated with greater morbidity and lower patient acceptance than HNS. The improvement in AHI with HNS, as shown in the STAR trial, is similar to the improvement in AHI following MMA. Clinical input also supports that HNS results in a meaningful improvement in health outcomes in appropriately selected adolescents with OSA and Down’s syndrome who have difficulty in using CPAP. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome for patients meeting the following selection criteria which are based on information from clinical study populations and clinical expert opinion.

- Age ≥ 22 years in adults or adolescents with Down’s syndrome age 10 to 21; AND
- Diagnosed moderate to severe OSA (with less than 25% central apneas); AND
- CPAP failure or inability to tolerate CPAP; AND
- Body mass index ≤ 35 kg/m² in adults; AND
- Favorable pattern of palatal collapse

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 2.
Table 2. 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>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02344108</td>
<td>A Pilot Study to Evaluate the Safety and Efficacy of the Hypoglossal Nerve Stimulator in Adolescents and Young Adults With Down Syndrome and Obstructive Sleep Apnea</td>
<td>50</td>
<td>Sep 2020</td>
</tr>
<tr>
<td>NCT02907398</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>NCT03359096</td>
<td>Cardiovascular Endpoints for Obstructive Sleep Apnea With Twelfth Nerve Stimulation (CARDIOSA-12): A Randomized, Sham-Controlled, Double-Blinded, Crossover Trial</td>
<td>80</td>
<td>Jun 2020</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>NCT02263859</td>
<td>ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3)</td>
<td>141</td>
<td>Dec 2022</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

**2018 Input**

In response to requests, clinical input on moderate-to-severe and mild obstructive sleep apnea was received from 2 respondents, including 1 specialty society-level response, while this policy was under review in 2018.
Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice:

- Use of hypoglossal nerve stimulation for individuals with moderate-to-severe obstructive sleep apnea who have failed an adequate trial of (or are unable to tolerate) continuous positive airway pressure.

Based on the evidence and independent clinical input, the clinical input does not support that the following indication provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice:

- Use of hypoglossal nerve stimulation for individuals with mild obstructive sleep apnea who have failed an adequate trial of (or are unable to tolerate) continuous positive airway pressure.

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. The AASM practice parameters were based on a systematic review of the evidence that found that the published literature was comprised primarily of case series, with few controlled trials and varying approaches to preoperative evaluation and postoperative follow-up.

Using the change in 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” reflect 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 indicated 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 first line treatment. The AAP recommended 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 was recommended in addition to other therapy if a child/adolescent with OSA is overweight or obese.

American Academy of Otolaryngology - Head and Neck Surgery

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS; 2014) has a revised position statement on surgical management of OSA.25

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,
• maxillary and mandibular advancement

In a 2016 position statement, AAO-HNS supported hypoglossal nerve stimulation as an effective second-line treatment of moderate to severe obstructive sleep apnea in patients who are intolerant or unable to achieve benefit with CPAP.\textsuperscript{26}

AAO-HNS noted that not all patients are candidates for upper airway stimulation therapy and require a number of assessments to ensure proper patient selection.

\textit{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.\textsuperscript{27}

The guideline indicated 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%. 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.
**Medicare National Coverage**

In 2008, the Centers for Medicare and Medicaid Services (CMS) published a decision memorandum that addressed how to define moderate to severe OSA as a guide for a coverage policy for CPAP.\(^{28}\)

Because surgical approaches are considered when CPAP fails, the CMS policy was 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 Apnea/Hypopnea Index (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 14 and associated symptoms, CMS concluded that the data from RCTs have demonstrated improved daytime somnolence and functioning in those treated with CPAP.

There is no national coverage determination for hypoglossal nerve stimulation. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Regulatory Status**

The regulatory status of minimally invasive surgical interventions is shown in Table 3.

**Table 3. Minimally Invasive Surgical Interventions for Obstructive Sleep Apnea**

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Devices (predicate or prior name)</th>
<th>Manufacturer (previously owned by)</th>
<th>Indication</th>
<th>PMA/ 510(k)</th>
<th>FDA Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser-assisted uvulopalatoplasty (LAUP)</td>
<td>Various</td>
<td></td>
<td>Simple snoring and for the base of the tongue for OSA</td>
<td>K982717</td>
<td>1998 GEI</td>
</tr>
<tr>
<td>Radiofrequency ablation</td>
<td>Somnoplasty®</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interventions</td>
<td>Devices (predicate or prior name)</td>
<td>Manufacturer (previously owned by)</td>
<td>Indication</td>
<td>PMA/510(k)</td>
<td>FDA Product Code</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------------------------</td>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Palatal Implant</td>
<td>Pillar® Palatal Implant</td>
<td>Pillar Palatal (Restore Medical/ Medronic)</td>
<td>Stiffening the soft palate which may reduce the severity of snoring and incidence of airway obstructions in patients with mild to moderate OSA</td>
<td>K040417</td>
<td>LRK</td>
</tr>
<tr>
<td>Tongue base suspension</td>
<td>AIRvance ® (Repose)</td>
<td>Medronic</td>
<td>OSA and/or snoring. The AIRvance TM Bone Screw System is also suitable for the performance of a hyoid suspension</td>
<td>K122391</td>
<td>LRK</td>
</tr>
<tr>
<td></td>
<td>Encore™ (PRELUDE III)</td>
<td>Siesta Medical</td>
<td>Treatment of mild or moderate OSA and/or snoring</td>
<td>K111179</td>
<td>ORY</td>
</tr>
<tr>
<td>Interventions</td>
<td>Devices (predicate or prior name)</td>
<td>Manufacturer (previously owned by)</td>
<td>Indication</td>
<td>PMA/510(k)</td>
<td>FDA Product Code</td>
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<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Hypoglossal nerve stimulation (HNS)</td>
<td>Inspire II Upper Airway Stimulation</td>
<td>Inspire Medical Systems</td>
<td>“a subset of patients with moderate to severe obstructive sleep apnea” (AHI ≥ 20 and ≤ 65) in adult patients 22 years of age and older who have failed (AHI &gt; 20 despite CPAP usage) or cannot tolerate (&lt; 4 h use per night for ≥ 5 nights per week) CPAP and do not have complete concentric collapse at the soft palate level. Failure includes unwillingness to use CPAP.</td>
<td>P130008</td>
<td>2014 MNQ</td>
</tr>
<tr>
<td></td>
<td>aura6000®</td>
<td>ImThera Medical</td>
<td>IDE</td>
<td>2014</td>
<td></td>
</tr>
</tbody>
</table>

AHI: Apnea/Hypopnea Index; CPAP: continuous positive airway pressure; IDE: investigational device exemption; LAUP: Laser-assisted uvulopalatoplasty; OSA: obstructive sleep apnea.

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>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</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>
<tr>
<td>01/01/19</td>
<td>Annual Review, approved December 13, 2018. Policy approved with no changes at this time; however, the approval included the addition of future edits to the policy statements.</td>
</tr>
<tr>
<td>02/01/19</td>
<td>Annual Review, approved January 8, 2019. Policy updated with literature review through October 2018; References added and some references removed. Hypoglossal nerve stimulation is considered medically necessary under specified conditions.</td>
</tr>
<tr>
<td>05/01/19</td>
<td>Minor update, clarified Site of Service requirements.</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). ©2019 Premera All Rights Reserved.

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  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  • Qualified interpreters
  • Information written in other languages

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Civil Rights Coordinator - Complaints and Appeals
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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/portal/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)
Complaint forms are available at

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요리 (Creole):
Kreyol ayisyen:
Avi sila a gen Enfomasyon Enpòtan ladan. Avi sila a kapab genyen enfomasyon enpòtan konsénan aplikasyon w lan oswa konsénan kouvèti asirans lan atrave Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewwa enfomasyon sa a ak asistans nan lang ou paale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

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