MEDICAL POLICY – 7.01.101
Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

BCBSA Ref. Policy: 7.01.101

Effective Date: Sept. 1, 2020
Last Revised: Aug. 4, 2020
Replaces: 7.01.554

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

Select a hyperlink below to be directed to that section.

POLICY CRITERIA  |  DOCUMENTATION REQUIREMENTS  |  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.
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><strong>Medically necessary sites of service:</strong></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>
<td></td>
</tr>
<tr>
<td>• On campus-outpatient hospital/medical center</td>
<td></td>
</tr>
<tr>
<td>• Ambulatory Surgical Center</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inpatient hospital/medical center</th>
<th>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):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Anesthesia Risk</td>
<td>o ASA classification III or higher (see definition)</td>
</tr>
<tr>
<td>• Personal history of complication of anesthesia</td>
<td></td>
</tr>
<tr>
<td>• Documentation of alcohol dependence or history of cocaine use</td>
<td></td>
</tr>
<tr>
<td>• Prolonged surgery (&gt;3 hours)</td>
<td></td>
</tr>
<tr>
<td>• Cardiovascular Risk</td>
<td></td>
</tr>
</tbody>
</table>
### Site of Service for Elective Surgical Procedures

<table>
<thead>
<tr>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Uncompensated chronic heart failure (<a href="#">NYHA class</a> III or IV)</td>
</tr>
<tr>
<td>- Recent history of myocardial infarction (MI) (&lt;3 months)</td>
</tr>
<tr>
<td>- Poorly controlled, resistant hypertension*</td>
</tr>
<tr>
<td>- Recent history of cerebrovascular accident (&lt; 3 months)</td>
</tr>
<tr>
<td>- Increased risk for cardiac ischemia (drug eluting stent placed &lt; 1 year or angioplasty &lt;90 days)</td>
</tr>
<tr>
<td>- Symptomatic cardiac arrhythmia despite medication</td>
</tr>
<tr>
<td>- Significant valvular heart disease</td>
</tr>
</tbody>
</table>

- **Liver Risk**
  - Advance liver disease (MELD Score > 8)**

- **Pulmonary Risk**
  - Chronic obstructive pulmonary disease (COPD) (FEV1 <50%)
  - Poorly controlled asthma (FEV1 <80% despite treatment)
  - Moderate to severe obstructive sleep apnea (OSA)***

- **Renal Risk**
  - End stage renal disease (on dialysis)

- **Other**
  - Morbid obesity (BMI ≥ 50)
  - Pregnancy
  - Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria])
  - Anticipated need for transfusion(s)

* 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>Palatopharyngoplasty</td>
<td>Palatopharyngoplasty (eg, uvulopalatopharyngoplasty, uvulopharyngoplasty, uvulopalatal flap, expansion sphincter pharyngoplasty, lateral pharyngoplasty, palatal advancement pharyngoplasty, relocation pharyngoplasty) may be considered medically necessary 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.</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 failed an adequate trial of CPAP or failed an adequate trial of an oral appliance.</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>Hypoglossal nerve stimulation</td>
<td>Hypoglossal nerve stimulation may be considered medically necessary in adults with OSA under the following conditions:</td>
</tr>
<tr>
<td></td>
<td>• Age ≥ 22 years; and</td>
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<tr>
<td></td>
<td>• AHI ≥15 with less than 25% central apneas; and</td>
</tr>
<tr>
<td>Treatment</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>-----------</td>
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</tr>
<tr>
<td>• CPAP failure (residual AHI ≥ 20 or inability to tolerate CPAP ≥ 4hrs per night for ≥ 5 nights per week) or inability to tolerate CPAP; and</td>
<td></td>
</tr>
<tr>
<td>• Body mass index (BMI) ≤ 32 kg/m²; and</td>
<td></td>
</tr>
<tr>
<td>• Non-concentric retropalatal obstruction on drug induced sleep endoscopy (see Related Information)</td>
<td></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
- AHI >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 noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliant use, or refusal use the device; 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.**

**Surgical treatment of OSA that does not meet any of the above criteria may be considered not medically necessary.**

<table>
<thead>
<tr>
<th>All interventions in the absence of documented OSA</th>
<th>All interventions for the treatment of snoring in the absence of documented OSA (snoring alone is not considered a medical condition) are considered not medically necessary, including:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• LAUP (laser-assisted uvulopalatoplasty)</td>
<td></td>
</tr>
<tr>
<td>• Palatal stiffening procedures</td>
<td></td>
</tr>
<tr>
<td>• Radiofrequency volumetric tissue reduction of the palate</td>
<td></td>
</tr>
</tbody>
</table>
Treatment

Minimally-invasive surgical procedures

Investigational

The following minimally-invasive surgical procedures are investigational for the sole or adjunctive treatment of OSA or upper airway resistance syndrome (UARS):

- 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)
  - Implantation of palatal implants (eg, Pillar® Palatal Implant)
  - Injection of a sclerosing agent
- Radiofrequency volumetric tissue reduction of the tongue (eg, Somnoplasty®), with or without radiofrequency reduction of the palatal tissues
- 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

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
Clinically significant OSA is defined as those patients who have:

- Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of 15 or more events per hour, or
- AHI or RDI of at least 5 events per hour with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

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. The Apnea/Hypopnea Index is the total number of events (apnea or hypopnea) per hour of recorded sleep. The Respiratory Disturbance Index is the total number of 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 U.S. Food and Drug Administration.

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
Table 1. Terminology and Diagnostic Criteria for Obstructive Sleep Apnea

<table>
<thead>
<tr>
<th>Terms</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apnea</td>
<td>The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by ≥90% of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as ≥2 missed breaths, regardless of its duration in seconds.</td>
</tr>
<tr>
<td>Hypopnea</td>
<td>Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 4% arterial oxygen desaturation or an arousal. Hypopneas in children are scored by a ≥50% drop in nasal pressure and either a ≥3% decrease in oxygen saturation or an associated arousal.</td>
</tr>
<tr>
<td>Apnea/Hypopnea Index (AHI)</td>
<td>The average number of apneas or hypopneas per hour of sleep</td>
</tr>
<tr>
<td>Obstructive sleep apnea (OSA)</td>
<td>Repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep</td>
</tr>
</tbody>
</table>
| Mild OSA                 | In adults: AHI of 5 to <15  
In children: AHI ≥1.5 is abnormal                                                                                                                                   |
| Moderate OSA             | AHI of 15 to <30                                                                                     |
| Severe OSA               | Adults: AHI ≥30  
Children: AHI of ≥15                                                                                          |
| Positive airway pressure (PAP) | Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or Bi-level (Bi-PAP).                                                                                     |
| PAP Failure              | Usually defined as an AHI greater than 20 events per hour while using PAP                                                                                                                                  |
| PAP Intolerance          | PAP use for less than 4 h per night for 5 nights or more per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA                                             |

OSA: obstructive sleep apnea; PSG: Polysomnographic

Table 2. Scoring criteria and definitions of Terms for OSA

<table>
<thead>
<tr>
<th>Terms</th>
<th>Definitions and Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory event</td>
<td></td>
</tr>
<tr>
<td>Terms</td>
<td>Definitions and Criteria</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Apnea</td>
<td>The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds.</td>
</tr>
<tr>
<td>Hypopnea</td>
<td>Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 4% arterial oxygen desaturation or an arousal. Hypopneas in children 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.</td>
</tr>
<tr>
<td>RERA</td>
<td>Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increasing respiratory effort, terminating in an arousal but not otherwise meeting criteria for apnea or hypopnea.</td>
</tr>
<tr>
<td><strong>Respiratory event reporting</strong></td>
<td></td>
</tr>
<tr>
<td>AHI</td>
<td>The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep.</td>
</tr>
<tr>
<td>RDI</td>
<td>The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.</td>
</tr>
<tr>
<td>REI</td>
<td>The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in home sleep studies when actual sleep time from EEG is not available.</td>
</tr>
<tr>
<td>OSA</td>
<td>Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep.</td>
</tr>
<tr>
<td>UARS</td>
<td>Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.</td>
</tr>
<tr>
<td><strong>Positive airway pressure (PAP)</strong></td>
<td></td>
</tr>
<tr>
<td>APAP</td>
<td>Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP.</td>
</tr>
<tr>
<td>PAP</td>
<td>Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP).</td>
</tr>
<tr>
<td>PAP failure</td>
<td>Usually defined as an AHI &gt;20 events per hour while using PAP.</td>
</tr>
<tr>
<td>PAP intolerance</td>
<td>CPAP use for &lt;4 hours per night for ≥5 nights per week, or refusal to use PAP. PAP intolerance may be observed in patients with mild, moderate, or severe OSA.</td>
</tr>
</tbody>
</table>
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 (HNS). 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. The hallmark symptom of obstructive sleep apnea (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.
Summary of Evidence

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 (AHI) 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 with 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 was 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 visual analog scale than the second trial. Additional study is needed to corroborate the 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 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 nonrandomized 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. Prospective comparative trials are needed. For children and adolescents with OSA and Down Syndrome who are unable to tolerate CPAP, the evidence includes a safety study with 20 patients who were treated at tertiary care centers. The success rate was 70% with 2 adverse events of the leads, which were resolved with further surgery. Study in a larger number of patients with Down Syndrome is ongoing. 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 4.

Table 4. 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>NCT03760328</td>
<td>Effect of Upper Airway Stimulation: A Randomized Controlled Crossover Study</td>
<td>100</td>
<td>Jun 2020</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 2021</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>Dec 2021</td>
</tr>
<tr>
<td>NCT03868618*</td>
<td>A Multicenter Study to Assess the Safety and Effectiveness of the Genio Dual-sided Hypoglossal Nerve Stimulation System for the Treatment of Obstructive Sleep Apnea in Adults Subjects</td>
<td>136</td>
<td>Jun 2022</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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<tr>
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</tr>
<tr>
<td>NCT02263859</td>
<td>ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3)</td>
<td>138</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>NCT04031040</td>
<td>A Post-market Clinical Follow up of the Genio™ System for the Treatment of Obstructive Sleep Apnea in Adults.</td>
<td>110</td>
<td>Oct 2023</td>
</tr>
<tr>
<td>NCT02907398</td>
<td>Adherence and Outcome of Upper Airway Stimulation (UAS) for OSA International Registry</td>
<td>5000</td>
<td>Sep 2025</td>
</tr>
</tbody>
</table>

**Unpublished**

| ACTRN12614000338662 | Multi-level airway surgery in patients with moderate-severe Obstructive Sleep Apnoea (OSA) who have failed medical management to assess change in OSA events and daytime sleepiness. | 102 | Aug 2018 |

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

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**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**

Clinical input was sought to help determine whether the use of hypoglossal nerve stimulation for individuals with obstructive sleep apnea would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 2 respondents, including 1 specialty society-level response and physicians with academic medical center affiliation.

For individuals who have OSA who receive HNS, clinical input supports that this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in subgroups of appropriately selected patients. One
subgroup includes 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. Another subgroup includes appropriately selected adolescents with OSA and Down’s syndrome who have difficulty in using CPAP. The following patient selection criteria 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 ≤ 32 kg/m2 in adults; AND
- Favorable pattern of palatal collapse

**Practice Guidelines and Position Statements**

**American Academy of Sleep Medicine (AASM)**

The American Academy of Sleep Medicine (AASM) (2010) published practice parameters for surgical modifications of the upper airway for obstructive sleep apnea (OSA). The AASM practice parameters were based on a systematic review of the evidence that found 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” 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

The American Academy of Pediatrics (2012) published a clinical practice guideline on the diagnosis and management of childhood OSA.32

The Academy 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 Academy 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.33 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 2019 position statement, AAO-HNS supported hypoglossal nerve stimulation as an effective second-line treatment of moderate-to-severe OSA.³⁴

**American Society for Metabolic and Bariatric Surgery**

The American Society for Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA.³⁵ The guideline indicated that OSA is strongly associated with obesity, with the incidence of OSA in the morbidly obese population reported as between 38% and 88%. The Society 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.

**National Institute for Health and Care Excellence**

2017 guidance from the U.K.’s National Institute for Health and Care Excellence (NICE) concluded that evidence on the safety and efficacy of hypoglossal nerve stimulation is limited in quantity and quality.³⁶
Medicare National Coverage

The Centers for Medicare & Medicaid Services (CMS; 2008) published a decision memorandum that addressed how to define moderate to severe OSA as a guide for a coverage policy for CPAP. Because surgical approaches are considered when CPAP fails, the CMS policy was adapted to this policy on the surgical management of OSA. The CMS review of the literature suggested that there is a risk of hypertension with an Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index of at least 15 events per hour, and thus treatment is warranted for patients without any additional signs and symptoms. For patients with an AHI or Respiratory Disturbance Index 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.

Regulatory Status

The regulatory status of minimally invasive surgical interventions is shown in Table 5.

Table 5. Minimally Invasive Surgical Interventions for Obstructive Sleep Apnea

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Devices (predicate or prior)</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></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Radiofrequency ablation</td>
<td>Somnoplasty ®</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>Interventions</td>
<td>Devices (predicate or prior)</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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<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Palatal Implant</td>
<td>Pillar® Palatal Implant</td>
<td>Pillar Palatal (Restore Medical/ Medtronic)</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>2004 LRK</td>
</tr>
<tr>
<td>Tongue base suspension</td>
<td>AIRvance ® (Repose)</td>
<td>Medtronic</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>1999 LRK</td>
</tr>
<tr>
<td>Encore™ (PRELUDE III)</td>
<td>Siesta Medical</td>
<td>Siesta Medical</td>
<td>Treatment of mild or moderate OSA and/or snoring</td>
<td>K111179</td>
<td>2011 ORY</td>
</tr>
<tr>
<td>Hypoglossal nerve stimulation (HNS)</td>
<td>Inspire II Upper Airway Stimulation</td>
<td>Inspire Medical Systems</td>
<td>&quot;a subset of patients with moderate to severe obstructive sleep apnea&quot; (AHI ≥ 15 and ≤ 65) in adult patients 22 years of age and older who have failed (AHI &gt; 15 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-S021</td>
<td>2014 MNQ</td>
</tr>
<tr>
<td>Hypoglossal nerve stimulation</td>
<td>aura6000®</td>
<td>ImThera Medical</td>
<td>IDE 2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Genio™</td>
<td>Nyxoa</td>
<td>European CE Mark</td>
<td></td>
<td>2019</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.
The expanded indication for hypoglossal nerve stimulation in patients age 18 to 21 was based on patients with Down Syndrome and is contingent on a post-approval study of the Inspire® UAS in this age group. The post-approval study will be a multicenter, single-arm, prospective registry with 60 pediatric patients age 18 to 21. Visits will be scheduled at pre-implant, post-implant, 6 months, and yearly thereafter through 5 years.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/20</td>
<td>New policy number (7.01.101), approved May 12, 2020, effective June 1, 2020. This policy replaces policy 7.01.554. Policy statements remain unchanged except for clarifying minor edits; this is effectively a policy renumber.</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). ©2020 Premera All Rights Reserved.

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  - 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

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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/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:
http://www.hhs.gov/ocr/office/filerequest.html

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

Oromo (Cushite):

Français (French):

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Avi sila a gen Enfòmasyon Enpòtan ladann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan av si a. Ou ka gen pou pran kék aksyon avan seten dat limit pou ka kente kouivet’i asirans sante w la oswa pou yo ka ede w avel depans yo. Se dwa w pou resewa enfòmasyon sa a ak asisants nan lang ou pale a, san ou pa gen pou peye pout sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

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Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga imporsion maipanggep iti aplikasyonyo wenn coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelta iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga adda rowon tapno mapagtalaineyo ti coverage ti salun-atyo wennu tungon kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga imporsion ken tungon iti bukdoyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga osa 800-722-1471 (TTY: 800-842-5357).

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ประกาศนี้มีข้อความสำคัญ ประกาศนี้มีข้อความสำคัญเกี่ยวกับการขอความช่วยเหลือของประกันสุขภาพของคุณ Premera Blue Cross และมีข้อความสำคัญเกี่ยวกับการขอความช่วยเหลือของคุณการขอความช่วยเหลือของคุณที่มีสิทธิ์ต่อ ขอให้คุณตรวจสอบข้อความที่สำคัญและข้อมูลที่เกี่ยวข้องในการขอความช่วยเหลือของคุณ

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Tok Pisin (Tok Pisin):
Awa papaen biem plesi baikey koe. Tikina avisona pi baikey i mi ci koe. Tikina avisona pi baikey i mi ci koe. Tikina avisona pi baikey i mi ci koe. Tikina avisona pi baikey i mi ci koe. Tikina avisona pi baikey i mi ci koe.