MEDICAL POLICY – 7.01.554

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Effective Date: Dec. 1, 2017*
Last Revised: March 1, 2018
Replaces: N/A

*This policy has been revised. Click here to view the upcoming changes.

Related Medical Policies:
11.01.524 Site of Service - Select Surgical Procedures

Select a hyperlink below to be directed to that section.

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

Infinitum: 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.
## Policy Coverage Criteria

<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).</td>
</tr>
<tr>
<td><strong>Note:</strong> Clinically significant OSA is defined in the Related Information section.</td>
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</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.</td>
</tr>
<tr>
<td><strong>Note:</strong> Clinically significant OSA is defined in the Related Information section.</td>
<td></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.</td>
</tr>
<tr>
<td><strong>Note:</strong> Clinically significant OSA is defined in the Related Information section.</td>
<td></td>
</tr>
<tr>
<td><strong>All interventions in the absence of documented OSA</strong></td>
<td>All interventions, including LAUP (laser-assisted uvulopalatoplasty), radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures are considered not medically necessary for the treatment of snoring in the absence of documented OSA; snoring alone is not considered a medical condition.</td>
</tr>
<tr>
<td>Treatment</td>
<td>Investigational</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Implantable hypoglossal nerve stimulators</td>
<td>Implantable hypoglossal nerve stimulators are investigational for all indications, including but not limited to the treatment of obstructive sleep apnea (OSA).</td>
</tr>
<tr>
<td>Minimally-invasive surgical procedures</td>
<td>The following minimally-invasive surgical procedures are investigational for the sole or adjunctive treatment of OSA or upper airway resistance syndrome (UARS):</td>
</tr>
<tr>
<td></td>
<td>- Radiofrequency volumetric tissue reduction of the tongue (eg, Somnoplasty), with or without radiofrequency reduction of the palatal tissues</td>
</tr>
<tr>
<td></td>
<td>- Laser-assisted uvulopalatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues</td>
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<tr>
<td></td>
<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 Procedure)</td>
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<tr>
<td></td>
<td>- Tongue base suspension (eg, Airvance System, formerly the Repose™ Tongue and Hyoid Suspension System, Encore™ system)</td>
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<tr>
<td></td>
<td>- All other minimally-invasive surgical procedures not described above</td>
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</tbody>
</table>

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Description</td>
</tr>
<tr>
<td>0466T</td>
<td>Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0467T</td>
<td>Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>21199</td>
<td>Osteotomy, mandible, segmental; with genioglossus advancement</td>
</tr>
<tr>
<td>41512</td>
<td>Tongue base suspension, permanent suture technique</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</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 with OSA. A smaller number of patients may use oral appliances as a first-line treatment (see Related Policies).

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

**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:
  o History of stroke; or
  o Hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg); or
  o Ischemic heart disease; or
  o Symptoms of impaired cognition, mood disorders, or insomnia; or
  o Excessive daytime sleepiness (documented by either Epworth greater than 10 or MSLT less than 6); or
  o 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
  o Obesity (BMI greater than 35)

OSA severity is defined as:
• Mild for AHI ≥ 5/hr and < 15/hr.
• Moderate for AHI ≥ 15/hr and < 30/hr.
• Severe for AHI ≥ 30/hr.

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

Children

The presentation of OSA in pediatric patients may differ from that of adults.
The diagnosis of obstructive sleep apnea in children is established by a sleep study result showing an apneic/hypopneic index (AHI) greater than 1.5. (An AHI of 1.5 is considered severe in children.)

**Upper Airway Resistance Syndrome (UARS)**

Clinically significant upper airway resistance syndrome (UARS) is defined as greater than 10 EEG arousals per hour. The presence of abnormally negative intrathoracic pressures (ie, more negative than 10 cm) in conjunction with the EEG arousals supports the diagnosis. The measurement of intrathoracic pressures requires the use of an esophageal manometer as an adjunct to a polysomnogram. Objective evidence of hypopharyngeal obstruction is documented by either fiberoptic endoscopy or cephalometric radiographs.

**Evidence Review**

**Description**

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

**Background**

Obstructive sleep apnea (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. In patients with OSA, the normal pharyngeal narrowing may be accentuated by anatomic factors, such as a short, fat “bull” neck, elongated palate and uvula, and large tonsillar pillars with redundant
lateral pharyngeal wall mucosa. In addition, OSA is associated with obesity. OSA may also be associated with a variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. Obstruction anywhere along the upper airway can result in apnea.

The hallmark symptom of OSA is excessive daytime sleepiness, and the typical clinical sign of OSA is snoring, which can abruptly cease and be followed by gasping associated with a brief arousal from sleep. The snoring resumes when the patient falls back to sleep, and the cycle of snoring/apnea/arousal may be repeated as frequently as every minute throughout the night. Sleep fragmentation associated with the repeated arousal during sleep can lead to impairment of daytime activity. For example, adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, ie, cars, trucks, or heavy equipment. OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

Hypoglossal Nerve Stimulation

Section Summary

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

Summary of Evidence

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

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
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<tr>
<td>NCT02907398&lt;sup&gt;a&lt;/sup&gt;</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>NCT02263859&lt;sup&gt;a&lt;/sup&gt;</td>
<td>ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3)</td>
<td>141</td>
<td>May 2021</td>
</tr>
<tr>
<td>NCT02413970</td>
<td>Inspire® Upper Airway Stimulation System (UAS): Post-Approval Study Protocol Number 2014-001</td>
<td>127</td>
<td>Dec 2021</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01446601&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Pivotal Study of the Apnex Medical™ Hypoglossal Nerve Stimulation (HGNS) System to Treat Obstructive Sleep Apnea</td>
<td>132</td>
<td>Aug 2013 (terminated)</td>
</tr>
<tr>
<td>NCT02293746&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Inspire® Upper Airway Stimulation (UAS) System German Post-Market Study: CE Certificate Number 562872</td>
<td>60</td>
<td>Jan 2017 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
<sup>a</sup> Denotes industry-sponsored or cosponsored trial.
Practice Guidelines and Position Statements

American Academy of Sleep Medicine (AASM)

The American Academy of Sleep Medicine (AASM) published practice parameters for surgical modifications of the upper airway for obstructive sleep apnea (OSA) in 2010.\textsuperscript{23} 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.\textsuperscript{24} Using the change in Apnea-Hypopnea Index (AHI) as the primary measure of efficacy, substantial and consistent reductions were observed following mandibular-maxillary advancement (MMA), and adverse events were uncommonly reported. Outcomes following pharyngeal surgeries were less consistent, and adverse events were more commonly reported. The review found that outcomes of studies with newer pharyngeal techniques and multilevel procedures, performed in small numbers of patients, appear promising. The practice parameters noted the lack of rigorous data evaluating surgical modifications of the upper airway, resulting in a recommendation of “option” (uncertain clinical use) for MMA, uvulopalatopharyngoplasty (UPPP) as a sole procedure, or multilevel or stepwise surgery if patients failed UPPP as a sole treatment. Use of radiofrequency ablation was recommended as an “option” for patients with mild-to-moderate OSA who cannot tolerate or are unwilling to adhere to continuous positive airway pressure (CPAP), or in whom oral appliances have been found ineffective or undesirable. Palatal implants were recommended as an “option” for patients with mild OSA who failed medical therapy. Laser-assisted uvulopalatoplasty was not recommended as a routine treatment for OSA (standard). The practice parameters recommended as “standard” the need to determine the presence and severity of OSA before initiating surgical therapy, discussion of success rates, complications, and alternative treatments with the patient, and a postoperative follow-up evaluation, which includes a clinical evaluation and an objective measure of the presence and severity of sleep-disordered breathing and oxygen saturation. However, little guidance was available in the medical literature to recommend any particular monitoring strategy. The optimal interval and duration of this follow-up were also not clear from the available literature.
The American Academy of Pediatrics (AAP)

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

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

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

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) has a 2014 revised policy statement on surgical management of OSA. Procedures AAO-HNS supported as effective and not considered investigational when part of a comprehensive approach in the medical and surgical management of adults with OSA include tracheotomy, nasal and pharyngeal airway surgery, tonsillectomy and adenoidectomy, palatal advancement, UPPP, uvulopalatoplasty (including laser-assisted and other techniques), genioglossal advancement, hyoid myotomy, midline glossectomy, tongue suspension, and maxillary and mandibular advancement.

In its 2012 position statement on UPPP, AAO-HNS concluded that UPPP is a valid treatment of OSA. Simultaneous and serial surgical procedures were considered medically necessary and effective for patients with mild to severe obstructive sleep apnea. Another 2012 position statement recommended tongue suspension as effective when considered as part of a
comprehensive approach in the medical and surgical management of adult patients with mild OSA and in adult patients with moderate and severe OSA who have evidence of tongue base or associated hypopharyngeal obstruction.\textsuperscript{28} AAO-HNS notes that results appear to diminish in obese patients, and this technique should receive a weaker recommendation for these patients.

In 2011, AAO-HNS published clinical practice guidelines on polysomnography (PSG) for sleep-disordered breathing before tonsillectomy in children.\textsuperscript{29} In addition to recommendations for PSG (see Related Policies), AAO-HNS made the following recommendation: clinicians should admit children with OSA documented on PSG for inpatient, overnight monitoring after tonsillectomy if they are younger than age 3 years or have severe OSA (AHI $\geq 10$, oxygen saturation nadir $<80\%$ or both).

\textit{American Society for Metabolic and Bariatric Surgery}

In 2012, the American Society for Metabolic and Bariatric Surgery published guidelines on the perioperative management of OSA.\textsuperscript{30} The guideline states that OSA is strongly associated with obesity with the incidence of OSA in the morbidly obese population being reported to be between 38\% and 88\%. They recommend bariatric surgery be the initial treatment of choice for OSA in this population, as opposed to surgical procedures directed at the mandible or tissues of the palate.

\textit{Medicare National Coverage}

In 2001, the Centers for Medicare and Medicaid Services (CMS) published a decision memorandum for CPAP that addressed the issue of how to define moderate to severe OSA as a guide to a coverage policy for CPAP.\textsuperscript{31} Since surgical approaches are considered when CPAP fails, the Medicare policy has been adapted to this policy on surgical management of OSA. The Medicare review of the literature suggested that there is a risk of hypertension with an AHI greater than 15, and thus treatment is warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 and associated symptoms, the CMS document concluded that the data from 3 RCTs demonstrated improved daytime somnolence and functioning in those treated with CPAP.
Regulatory Status

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

In 1999, AIRvance® (Medtronic; formerly the Repose™ Bone Screw System from Influence) was cleared for marketing by the FDA though the 510(k) process for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with prethreaded suture. It is indicated for the treatment of OSA and/or snoring. In 2011, the Encore™ Tongue Suspension System (Siesta Medical) was cleared for marketing by the FDA though the 510(k) process. The FDA determined that this device was substantially equivalent to the PRELUDE III Tongue Suspension System (Siesta Medical). FDA product codes: LRK, ORY.

The Pillar® Palatal Implant System (Restore Medical, St. Paul, MN, acquired by Medtronic, Minneapolis, MN), an implantable device, was cleared for marketing by the FDA through the 510(k) process. The labeled indication of the device is as follows: “The Pillar® Palatal Implant System is intended for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (obstructive sleep apnea).” FDA product code: LRK.

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

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/14/14</td>
<td>New PR policy replacing 7.01.101. Medically necessary criteria for OSA diagnosis expanded to include a threshold of an AHI of 15-30 events as a specific criterion. When the AHI is 5-15, an additional requirement of documentation to evidence: stroke, hypertension, ischemic heart disease; or, symptoms of impaired cognition/mood disorder/insomnia; or, Epworth sleep scale greater than 10 or MSLT less than 6 to evidence daytime sleepiness; or, more than 20 episodes of desaturation; or obesity (BMI over 35). When the AHI is greater than 30, the patient must be able to tolerate PAP or it must be contraindicated. Criteria for children updated to an apneic/hypopneic index (AHI) greater than 1.5. ICD-9 and ICD-10 procedure and diagnosis codes removed; they are not utilized in adjudication. Policy effective subsequent to 2.01.532 effective October 23, 2014. Added investigational policy</td>
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</tbody>
</table>

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<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/23/14</td>
<td>Reissue policy as updates are now effective; reference to previous version removed.</td>
</tr>
<tr>
<td>06/17/15</td>
<td>Annual Review. No change to policy statements. Informational CPT codes removed; these are not reviewed.</td>
</tr>
<tr>
<td>02/09/16</td>
<td>Annual Review. Policy updated with literature review through January, 2016; reference 31 added; policy statements unchanged.</td>
</tr>
<tr>
<td>03/01/17</td>
<td>Annual Review, approved February 14, 2017. Policy updated with literature review through October 4, 2016; references 17-20 added. Coding update; added codes, including new CPT codes effective 1/1/17. No change to policy statements.</td>
</tr>
<tr>
<td>03/30/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Removed Related Policies 1.01.524, 2.01.503, and 2.01.532 as they were archived.</td>
</tr>
<tr>
<td>03/01/18</td>
<td>Note added that this policy has been revised. Added link to revised policy that will become effective June 1, 2018.</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.

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


Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Amharic):

لا يوجد هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات مهمة بخصوص طبيك أو

العملية التي تريد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تاريخ مهمة

Premera Blue Cross ذهاب إلى إجراء في تواريخ محددة للحفاظ على تعدادك الصحية والسعة

في ذلك الكشف. قبل أن تأخذ الحصول على هذه المعلومات والمساعدة بذلك تود تلخيص كل كلمة. لاحظ

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

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的
申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期
之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母
語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Beekisini kun odefannoo barbaachisaa qaba. Beekisisti kun sagantaa
yooankaraa Premera Blue Cross tii tajajila keessoontaa ilaachisee
odeeffannoo barbaachisaa qabaachu danda’a. Guyaayawann murteesaa
ta’an beekisista kan keessatti ilaaakaa. Taa kaffaltii daa deeggarmum
yooank tajajila fayyaa keessanif gyyaa dhumaa irratti waaq waawat
jraachu danda’a. Kaffaltii irraa bilisa halaa ta’aen faa’an keessanii
odeeffannoo aragchuha fii deeggarsaa aragchuha minga ni qabaaatu.
Lakkoofisa bilbiila 800-722-1471 (TTY: 800-842-5357) ti bilbiila.

Français (French):

Cet avis a d’importantes informations. Cet avis peut avoir d’importantes
informations sur votre demande ou la couverture par l’intermédiaire de
Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous
devrez peut-être prendre des mesures par certains délais pour maintenir
votre couverture de santé ou d’aide avec les coûts. Vous avez le droit
d’obtenir cette information et de l’aide dans votre langue à aucun coût.
Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Avis sila a gen Enfòmasyon Enpòtan ladann. Avis 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
avis sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka
kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk despans yo.
Se dwa w pou resewva enfòmasyon sa a ak asirans lan ou lang ou pale a,
san ou pa gen pou pèye ou pou sa. Rate nan 800-722-1471
(TTY: 800-842-5357).

Deutsche (German):

Diese Benachrichtigung enthält wichtige Informationen. Diese
Benachrichtigung enthält unter Umständen wichtige Informationen
bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera
Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser
Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln
müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten
zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen
in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471
(TTY: 800-842-5357).

Hmoob (Hmong):

Tsab ntawv tshaj xo no muaj cov ntsiab lbs tuem ceeb. Tej zaum
tsab ntawv tshaj xo no muaj cov ntsiab lbs tuem ceeb bokj kaj dawm
thov kev kaj giv kaj cov kev kaj cv naa dawm Premera Blue Cross.
Tej zaum muaj cov hnv tuem ceeb cv naa dawm dawm cv.
Tej zaum kaj kaj cvnt kaj ncwau uaa giv yam uaa kaj cvnt cv tay sbu
dhaw cov cay yoo ngoo ngoo cvnt cay sbu tcw dawm daw dawm cv
mo nu sib sib cvnt cvnt kaj cvnt cvnt cvnt cvnt cvnt cvnt cvnt
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Illoko (Illocano):

Daytoy a Pakdaar ket naglaon iti Napateg nga Impormacion. Daytoy a
pakdaar mabalina nga adda ket naglaon iti napateg nga impormasion
maipanggep iti aplikasyonyo wonno coverage babaen iti Premera Blue
Cross. Daytoy ket mabalina dagiti importante a pelsa iti daytoy a pakdaar.

Mabalina nga adda rumbeng nga aramidenyo nga addang sakbay dagiti
partikular a naituding nga adda aldaw tapno mapagtalaindyo ti coverage ti
salun-atyo Wenno tulong kadagiti gastos. Adda karbenganyo a mangala ti
daytoy nga impormasion ken tulong ti bukodayo a pagasasao nga awan ti

Italiano (Italian):

Questo avviso contiene informazioni importanti. Questo avviso può contenere
informazioni importanti sulla tua domanda o copertura attraverso Premera Blue
Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe
essere necessario un tuo intervento entro una scadenza determinata per
consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto
di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiamata 800-722-1471 (TTY: 800-842-5357).
Aviso (Spanish): Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso.

Tiếng Việt (Vietnamese): Thông báo nầy cung cấp thông tin quan trọng. Thông báo nầy có thể thay đổi theo thông tin quan trọng về đơn xin tham gia hoặc thông tin khác của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo nầy.

Польский (Polish): To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Privacy Policy lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub przyjmowania decyzji wobec waszego pożycia.

Tagsalog (Tagalog): Ang Pagawa na ito ay naglalaman ng mahalagang impormasyon. Ang pagawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagkaopak sa pamamagitan ng Premera Blue Cross. Maaaring maayon ng mga impormasyon na ito upang mapahimok ang iyong pagsakop sa kalusugan o tulong na maayon sa 800-722-1471.

Русский (Russian): Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В этом уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется приветствовать важные предельные сроки для сохранения страхового покрытия или помощи с расходами. Если вы имеете право на бесплатное получение этой информации и помощь на вашем языке, звоните по телефону 800-722-1471.