**Protocol**

**Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome**

(701101)

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<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective Date: 07/01/15</th>
<th>Next Review Date: 05/19</th>
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<tr>
<td>Preauthorization</td>
<td>No</td>
<td>Review Dates: 03/07, 05/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18</td>
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**Preauthorization is not required.**

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
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<th>Populations</th>
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<td>Individuals: With obstructive sleep apnea</td>
<td>Interventions of interest are: • Laser-assisted uvulopalatoplasty</td>
<td>Comparators of interest are: • Continuous positive airway pressure • Established surgical procedures</td>
<td>Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity</td>
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<td>Interventions of interest are: • Hypoglossal nerve stimulation</td>
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**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 might be indicated. This protocol addresses minimally invasive surgical procedures for the treatment of OSA. The procedures include laser-assisted uvuloplasty, tongue base suspension, radiofrequency...
SUMMARY OF EVIDENCE

For individuals who have OSA who receive laser-assisted uvulopalatoplasty, tongue base suspension, radiofrequency volumetric reduction of palatal tissues and base of tongue, palatal stiffening procedures, or 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; further, none of these procedures has improved results on the Apnea-Hypopnea Index, which measures the severity of a person’s sleep apnea, nor has it reduced 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 the Apnea-Hypopnea Index (AHI), body mass index, and favorable pattern of palatal collapse also met criteria for significant decreases in AHI or Oxygen Desaturation Index (ODI). It should be noted that the role of nerve stimulation among the surgical procedures for OSA treatment is uncertain. RCTs comparing hypoglossal nerve stimulation with conventional surgical procedures are needed to evaluate benefits and harms. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Palatopharyngoplasty (e.g., 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 (OSA) syndrome in appropriately selected adults who have failed an adequate trial of continuous positive airway pressure (CPAP) or failed an adequate trial of an oral appliance. Clinically significant OSA is defined as patients who have:

- An Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of 15 or more events per hour, or
- An AHI or RDI of more than five (but less than 14) events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

Hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered medically necessary in appropriately selected adults 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. Clinically significant OSA is defined as patients who have:

- An AHI or RDI of 15 or more events per hour, or
- An AHI or RDI of more than five (but less than 14) events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.
Adenotonsillectomy may be considered **medically necessary** in pediatric patients with clinically significant OSA and hypertrophic tonsils. Clinically significant OSA is defined as those pediatric patients who have:

- An AHI or RDI of at least five per hour, or
- An AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.

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

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

- Laser-assisted palatoplasty or radiofrequency volumetric tissue reduction of the palatal tissues
- Tongue base suspension
- Radiofrequency volumetric tissue reduction of the tongue (with or without radiofrequency reduction of the palatal tissues)
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants
- All other minimally-invasive surgical procedures not described above.

Implantable hypoglossal nerve stimulators are considered **investigational** for all indications, including but not limited to the treatment of OSA.

All interventions, including laser-assisted palatoplasty, 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.

**POLICY GUIDELINES**

Continuous positive airway pressure (CPAP) is the preferred first-line treatment for most patients. Some patients may use oral appliances as a first line treatment (see the Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome Protocol).

The AHI measures the total number of events (apnea or hypopnea) per hour of recorded sleep. The RDI measures 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 to baseline, and with at least a 4% oxygen desaturation.

**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. OSA is associated with a heterogeneous group of anatomic variants producing obstruction. In patients with OSA, the normal pharyngeal narrowing may be accentuated by anatomic factors, such as a short, fat “bull” neck, elongated palate and uvula, and large tonsillar pillars with redundant lateral pharyngeal wall mucosa. In addition, OSA is associated with obesity. OSA may also be associated with craniofa-
cian abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. Obstruction anywhere along the upper airway can result in apnea.

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

Diagnosis

The diagnosis of OSA rests on a combination of clinical evaluation and objective criteria to identify those levels of obstruction considered to be clinically significant (see the Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome). The criterion standard diagnostic test for sleep disorders is polysomnography, which includes sleep staging to assess arousals from sleep, and determination of the frequency of apneas and hypopneas from channels measuring oxygen desaturation, respiratory airflow, and respiratory effort. An obstructive apnea is defined as at least a 10-second drop in ventilation (at least 90% drop of peak signal excursion) associated with the ongoing ventilatory effort. Obstructive hypopnea is a 30% or greater reduction of air exchange with an associated fall in oxygen saturation of at least 3% or 4%. Respiratory event-related arousals (RERAs) are scored if there is a sequence of breaths lasting at least 10 seconds characterized by increasing respiratory effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea or hypopnea. The AHI measures the total number of apneas and hypopneas per hour of sleep. The RDI measures the number of apneas, hypopneas, and RERAs per hour of sleep. When sleep onset and offset are unknown (e.g., in-home sleep studies), the RDI may be calculated based on the number of apneas and hypopneas per hour of recording time. OSA is considered to be clinically significant when an adult has an AHI of five or more, in addition to symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, documented hypertension, ischemic heart disease, or history of stroke. An AHI of 15 to 30 is typically considered moderate OSA, while an AHI of 30 or more is considered severe OSA. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as two or more missed breaths, regardless of its duration in seconds. Hypopneas are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or an associated arousal. In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 or more is considered severe.

A condition related to OSA has been termed upper airway resistance syndrome (UARS). UARS is characterized by a partial collapse of the airway resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha electrocardiogram arousals (RERAs). UARS can occur in the absence of snoring and in patients who are not overweight. The resistance to airflow is typically subtle and does not result in apneic or hypopneic events. However, increasingly negative intrathoracic pressure during inspiration can be measured using an esophageal manometer. RERAs can also be detected absent manometry during polysomnography. It has been proposed that UARS is a distinct syndrome from OSA that may be considered a disease of arousal. In the absence of intrathoracic pressure monitoring, a positive response to CPAP has also been used to support the diagnosis.
Nonsurgical Treatments

Nonsurgical treatment for OSA or UARS includes CPAP or orthodontic repositioning devices (see the Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome Protocol for a discussion).

Surgical Treatments

Traditional surgeries for OSA or UARS include uvulopalatopharyngoplasty (UPPP) and a variety of maxillofacial surgeries such as mandibular-maxillary advancement (MMA). UPPP involves surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. The amount of tissue removed is individualized for each patient, as determined by the potential space and width of the tonsillar pillar mucosa between the two palatal arches. UPPP enlarges the oropharynx but cannot correct obstructions in the hypopharynx; thus, patients who fail UPPP may be candidates for additional procedures, depending on the site of obstruction. Additional procedures include hyoid suspensions, maxillary and mandibular osteotomies, or modification of the tongue. Drug-induced sleep endoscopy and/or cephalometric measurements have been used as methods to identify hypopharyngeal obstruction in these patients. The first-line treatment in children is usually adenotonsillectomy. Minimally invasive surgical approaches are being evaluated for OSA in adults.

Laser-Assisted Uvulopalatoplasty

Laser-assisted uvulopalatoplasty (LAUP) is an outpatient procedure proposed as a treatment of snoring with or without associated OSA. In this procedure, superficial palatal tissues are sequentially reshaped using a carbon dioxide laser. The extent of the surgery is typically different from standard UPPP because only part of the uvula and associated soft palate tissues are reshaped. The procedure does not remove or alter tonsils or lateral pharyngeal wall tissues. The patient undergoes from three to seven sessions at three to four week intervals. One purported advantage of LAUP is that the amount of tissue ablated can be titrated so treatment can be discontinued once snoring is eliminated. LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, which raises its own issues of safety and, in particular, effectiveness.

Tongue Base Suspension

In this procedure, the base of the tongue is suspended with a suture that is passed through the tongue and fixed with a screw to the inner side of the mandible, below the tooth roots. The aim of the suspension is to make it less likely for the base of the tongue to prolapse during sleep.

Radiofrequency Ablation of Palatal Tissues and Base of Tongue

Radiofrequency ablation of the soft palate is similar in concept to LAUP, although a different energy source is used. Radiofrequency is used to produce thermal lesions within the tissues rather than using a laser to ablate the tissue surface, which may be painful. For this reason, radiofrequency ablation appears to be growing in popularity as an alternative to LAUP. In some situations, radiofrequency of the soft palate and base of tongue are performed together as a multilevel procedure.

Palatal Stiffening Procedures

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

Hypoglossal Nerve Stimulation

Stimulation of the hypoglossal nerve contracts the genioglossus muscle, the largest upper airway dilator muscle. This causes tongue protrusion and stiffening of the anterior pharyngeal wall, potentially decreasing apneic
events. Hypoglossal nerve stimulation systems include an implantable neurostimulator, stimulating leads, and electrodes. Stimulation systems such as the Inspire II Upper Airway Stimulation System include respiratory sensing leads that permit intermittent stimulation during inspiration. Stimulation parameters are titrated during an in-laboratory polysomnography and can be adjusted by the patient during home use. This stimulation system is turned on only during sleep periods.

REGULATORY STATUS

In 1998, the Somnoplasty® System 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 OSA. FDA product code: GEI.

In 1999, AIRvance® (Medtronic, Minneapolis, MN; 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, Los Gatos, CA) was cleared for marketing by the FDA though the 510(k) process. FDA determined that this device was substantially equivalent to the PRELUDE III Tongue Suspension System (Siesta Medical). FDA product codes: LRK, ORY.

The Pillar® Palatal Implant System (Restore Medical, St. Paul, MN [since acquired by Medtronic]), 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 FDA through the premarket approval process. In 2011, Apnex Medical (Roseville, MN) received FDA approval to conduct a randomized investigational device exemption trial for the Hypoglossal Nerve Stimulation (HGNS®) System. The trial was terminated, and Apnex Medical has ceased operations. In 2014, ImThera Medical (San Diego, CA) received FDA approval to conduct an investigational device exemption trial with the aura6000®.

RELATED PROTOCOL

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.
REFERENCES

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