FEP 7.01.101 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Effective Date: January 15, 2018
Related Policies:
2.01.18 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

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 evidence review addresses minimally invasive surgical procedures for the treatment of OSA. The procedures 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 evidence review does not address conventional surgical procedures such as uvulopalatopharyngoplasty, hyoid suspension, surgical modification of the tongue, maxillofacial surgery, or adenotonsillectomy.

FDA 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 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 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 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®.

**POLICY STATEMENT**

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 (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 5 (but <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, 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 5 (but <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 5 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 **not medically necessary** for all indications, including but not limited to the treatment of OSA.
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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 is the preferred first-line treatment for most patients. Some patients may use oral appliances as a first-line treatment (see evidence review 2.01.18).

The Apnea/Hypopnea Index measures the total number of events (apnea or hypopnea) per hour during recorded sleep. The Respiratory Disturbance Index measures the total number of events (apnea or hypopnea) per hour during the 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

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 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 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Sleep Medicine

The American Academy of Sleep Medicine published practice parameters for surgical modifications of the upper airway for obstructive sleep apnea (OSA) in 2010.23 The practice parameters were based on a 2010 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.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, and adverse events were uncommonly reported. Outcomes following pharyngeal surgeries were less consistent, and adverse events were more commonly reported. The review found that

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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 mandibular-maxillary advancement, 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. As a standard, laser-assisted uvulopalatoplasty was not recommended as a routine treatment for OSA. Other recommended standard practice parameters include: the need to determine the presence and severity of OSA before initiating surgical therapy; the 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 follow-up were also not clear from the available literature.

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

American Academy of Otolaryngology – Head and Neck Surgery
The 2016 American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) position statement on hypoglossal nerve stimulation for treatment of OSA stated that:

"...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 [body mass index] and objective upper airway evaluation measures are required for proper patient selection.”

AAO-HNS issued 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 OSA. Another position statement (updated in 2016) recommended tongue suspension as “effective ... when considered as part of a comprehensive approach in the medical and surgical management of adults with mild OSAHA [obstructive sleep apnea hypopnea syndrome] and in adults with moderate and severe OSA who have evidence of tongue base or associated hypopharyngeal obstruction.” AAO-HNS noted that results appear to diminish in obese patients, and this technique should receive a weaker recommendation for these patients.
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In 2011, AAO-HNS published clinical practice guidelines on polysomnography (PSG) for sleep-disordered breathing before tonsillectomy in children.\(^3\) In addition to recommendations for PSG (see evidence review 2.01.18), AAO-HNS made the following recommendation: clinicians should admit children with OSA documented on PSG for inpatient, overnight monitoring after tonsillectomy if they are younger than age 3 years or have severe OSA (AHI ≥10, oxygen saturation nadir <80% or both).

**American Society for Metabolic and Bariatric Surgery**

In 2012, the American Society for Metabolic and Bariatric Surgery published guidelines on the perioperative management of OSA.\(^3\) The guidelines 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.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

In 2001, the Centers for Medicare & Medicaid Services (CMS) published a decision memorandum that addressed how to define moderate-to-severe OSA as a guide for a coverage policy on CPAP.\(^3\) Because surgical approaches are considered when CPAP fails, CMS policy was adapted to this evidence review on the surgical management of OSA. The CMS review of the literature suggested that there is a risk of hypertension with an AHI greater than 15 events per hour, and thus treatment is warranted for patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 and associated symptoms, CMS concluded that the data from 3 randomized controlled trials have demonstrated improved daytime somnolence and functioning in those treated with CPAP.

**REFERENCES**


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POLICY HISTORY

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<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tr>
<td>December 2011</td>
<td>New Policy</td>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Update Policy</th>
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<tbody>
<tr>
<td>September 2014</td>
<td>Policy updated with literature search, adding references 13, 14, 29, 30, 35-38, and 40. New FDA approved device, Hypoglossal Nerve Stimulator has been added to policy. Policy statement has been updated to indicate it is not medically necessary.</td>
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<tr>
<td>September 2015</td>
<td>Policy updated with literature review; reference 31 added; policy statements unchanged.</td>
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<tr>
<td>December 2016</td>
<td>Policy updated with literature review, adding references 17-20. Medically necessary policy statement revised to include variants of palatopharyngoplasty.</td>
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<tr>
<td>December 2017</td>
<td>Policy updated with literature review through July 20, 2017; reference 26 added; reference 27 updated. Policy statements unchanged except Hypoglossal Nerve Stimulator policy statement corrected from investigational (as noted in Dec. 2016 version) back to not medically necessary per 2014 OPM guidance regarding devices with Premarket Approval</td>
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