7.01.101 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Summary
Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This policy addresses the various surgical procedures that have been evaluated for the treatment of adult and pediatric patients with OSA.

FDA REGULATORY STATUS
The Somnoplasty® device has been cleared for marketing by FDA for RFA of palatal tissues for simple snoring and for the base of the tongue for OSA. FDA product code: GEI.

AIRvance® (Medtronic; formerly the Repose™ Bone Screw System from Influence) was cleared for marketing through the FDA 510(k) process in 1999 with intended use 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. The Encore™ Tongue Suspension System (Siesta Medical) received clearance for marketing by FDA in 2011, citing the PRELUDE III Tongue Suspension System (Siesta Medical) as a predicate device. FDA product codes: LRK, ORY.

The Pillar® Palatal Implant System (originally Restore Medical, St. Paul, MN, acquired by Medtronic, Minneapolis, MN) is an implantable device that has been cleared for marketing through the FDA 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.

The Inspire® II Upper Airway Stimulation System (Inspire Medical Systems) received FDA approval in May 2014. 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 for an IDE trial with the aura6000®.
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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 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. Clinically significant OSA is defined as those patients who have:

- Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) 15 or more events per hour, or
- AHI or RDI 5 or more events and 14 or less 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 mandibularmaxillary 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. Clinically significant OSA is defined as those patients who have:

- AHI or RDI 15 or more events per hour, or
- AHI or RDI 5 or more events and 14 or less 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:

- AHI or RDI of at least 5 per hour, or
- 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 (UARS):

- Laser-assisted palatoplasty (LAUP) 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 LAUP, 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.
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POLICY GUIDELINES (IF NEEDED)
CPAP is the preferred first-line treatment for most patients. A smaller number of patients may use oral appliances as a first-line treatment (see Policy No. 2.01.18).

The AHI is the total number of events (apnea or hypopnea) per hour of recorded sleep. The RDI 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 as 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
There is a great range of severity of obstructive sleep apnea (OSA), with symptoms ranging from snoring only to severe excessive daytime sleepiness or hypertension. If OSA is considered mild (Apnea/Hypopnea Index [AHI] between 5 and 15) and snoring is the only manifestation, treatment would not be considered necessary. Adenotonsillectomy may be considered medically necessary in pediatric patients with OSA. Standard surgical procedures (ie, uvulopalatopharyngoplasty [UPPP] and maxillofacial procedures) have been found to improve symptoms in adult patients with clinically significant OSA. Because of the likelihood of adverse effects, surgery should be limited to patients who are unable to tolerate continuous positive airway pressure (CPAP). Minimally invasive surgical procedures have limited efficacy in patients with mild-to-moderate OSA and have not been shown to improve AHI or excessive daytime sleepiness in adult patients with moderate to severe OSA. Additional study is needed to determine whether adding minimally invasive procedures to UPPP improves the net health outcome compared with treatment with UPPP alone.

One system for hypoglossal nerve stimulation has been approved by the U.S. Food and Drug Administration. At this time, hypoglossal nerve stimulation has been studied only in case series, the largest series had 12-month follow-up. In addition, a pivotal study on the HGNS system was terminated and the company ceased operations when it was determined that the trial was unlikely to meet its primary end point. Additional study with existing devices is needed to permit conclusions regarding the effect of this treatment on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
American Academy of Sleep Medicine
The American Academy of Sleep Medicine (AASM) published practice parameters for surgical modifications of the upper airway for obstructive sleep apnea (OSA) in 2010. AASM practice parameters were based on a systematic review of the evidence that found that the published literature was comprised primarily of case series, with few controlled trials and varying approaches to preoperative evaluation and postoperative follow-up. Using the change in 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
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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.

American Academy of Pediatrics
The American Academy of Pediatrics (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.

American Academy of Otolaryngology–Head and Neck Surgery
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 OSA. Another 2012 position statement recommended tongue suspension as effective when considered as part of a comprehensive approach in the medical and surgical management of adults with mild OSA 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.

In 2011, AAO-HNS published clinical practice guidelines on polysomnography (PSG) for sleep-disordered breathing before tonsillectomy in children. 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 (ASMBS) published guidelines on the perioperative management of OSA. 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%. ASMBS recommended bariatric surgery as the initial treatment of choice for OSA in this population, as opposed to surgical procedures directed at the mandible or tissues of the palate.
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U.S. Preventive Services Task Force Recommendations

Not applicable.

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. Because 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.

REFERENCES

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Policy History

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tr>
<td>September 2014</td>
<td>Update Policy</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>Update Policy</td>
<td>Policy updated with literature review; reference 31 added; policy statements unchanged.</td>
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<tr>
<td>December 2016</td>
<td>Update Policy</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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Signature on File

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