Protocol

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

(701101)

Medical Benefit		**Effective Date**: 10/01/10	**Next Review Date**: 05/15
Preauthorization	Yes	**Review Dates**: 03/07, 05/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is required for uvulopalatopharyngoplasty, hyoid suspension, surgical modification of the tongue, and/or maxillofacial surgery such as mandibular-maxillary advancement.*** *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.*

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. This Protocol addresses the various surgical procedures that have been evaluated for the treatment of adult and pediatric patients with OSA.

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. Therefore, OSA is associated with a heterogeneous group of anatomic variants producing obstruction.

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, i.e., 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.

Diagnosis: The final diagnosis of OSA rests on a combination of clinical evaluation and objective criteria to identify those levels of obstruction that are considered to be clinically significant. The gold standard diagnostic test for sleep disorders is considered a polysomnogram, 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 respiration (at least 90% drop of peak signal excursion) associated with ongoing ventilatory effort.

Obstructive hypopnea is a 30% or greater reduction of air exchange with an associated fall in oxygen saturation of at least 34%. 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 apnea/hypopnea index (AHI) is defined as the total number of apneas and hypopneas per hour of sleep. The respiratory disturbance index (RDI) may be defined as 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 patient has an AHI greater than five and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI greater than or equal to 15 is typically considered moderate OSA, while an AHI greater than 50 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 an equal to or greater than 3% 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 (EEG) 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 continuous positive airway pressure (CPAP) has also been used to support the diagnosis.

Treatment: Nonsurgical treatment for OSA or UARS includes CPAP or orthodontic repositioning devices, which are addressed in a separate Protocol. 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. The 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. Fiberoptic 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 being evaluated for OSA in adults include the following:

Laser-assisted Uvulopalatoplasty (LAUP): LAUP is an outpatient alternative that has been 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 than standard UPPP, since only part of the uvula and associated soft-palate tissues are reshaped. The procedure, as initially described, 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 such that the 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.

Radiofrequency Ablation (RFA) of Palatal Tissues and the Tongue: RFA 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, RFA 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.

Tongue Base Suspension: In this procedure, the base of the tongue is suspended with a suture that is passed through the tongue and then fixated 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.

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

Regulatory Status

The Somnoplasty® device has been cleared for marketing by the U.S. Food and Drug Administration (FDA) for radiofrequency ablation of palatal tissues for simple snoring and for the base of the tongue for OSA.

The Repose™ Bone Screw System (Influence, San Francisco, CA) was cleared for marketing through the 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 pre-threaded suture. It is indicated for the treatment of OSA and/or snoring.

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)."

Related Protocol

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Policy (Formerly Corporate Medical Guideline)

Uvulopalatopharyngoplasty (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). Clinically significant OSA is defined as those patients who have:

- Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to five events and less than or equal to 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 adult patients with clinically significant OSA and objective documentation of hypopharyngeal obstruction who have not responded to or do not tolerate CPAP. Clinically significant OSA is defined as those patients who have:

- AHI or RDI greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to five events and less than or equal to 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:

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

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

- Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues
- Laser-assisted palatoplasty (LAUP) or radiofrequency volumetric tissue 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
- Tongue base suspension
- All other minimally-invasive surgical procedures not described above.

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.

Policy Guideline

Clinically significant obstructive sleep apnea (OSA) is defined as those adult patients who have:

- Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to five events and less than or equal to 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.

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

The presentation of OSA in pediatric patients may differ from that of adults. OSA in pediatric patients is defined as those who have:

- AHI or RDI of at least five per hour, or

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

Clinically significant upper airway resistance syndrome (UARS) is defined as greater than 10 EEG arousals per hour. The presence of abnormally negative intrathoracic pressures (i.e., 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.

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

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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