

# Protocol

## Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

(701101)

<b>Medical Benefit</b>		<b>Effective Date:</b> 12/01/19	<b>Next Review Date:</b> 01/21
<b>Preauthorization</b>	No	<b>Review Dates:</b> 03/07, 05/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18, 01/19, 09/19, 01/20	

### **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.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Laser-assisted uvulopalatoplasty	Comparators of interest are: • Continuous positive airway pressure • Conventional surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Radiofrequency volumetric reduction of palatal tissues and base of tongue	Comparators of interest are: • Continuous positive airway pressure • Conventional surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Palatal stiffening procedures	Comparators of interest are: • Continuous positive airway pressure • Conventional surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Tongue base suspension	Comparators of interest are: • Continuous positive airway pressure • Conventional surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Hypoglossal nerve stimulation	Comparators of interest are: • Conventional surgical procedures	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

### **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 evidence review 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 evidence review does not address conventional surgical procedures such as uvulopalatopharyngoplasty, hyoid suspension, surgical modification of the tongue, maxillofacial surgery, or adenotonsillectomy.

## SUMMARY OF EVIDENCE

For individuals who have OSA who receive laser-assisted uvulopalatoplasty, the evidence includes a single randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The trial indicates reductions in snoring, but limited efficacy on the Apnea/Hypopnea Index (AHI) or symptoms in patients with mild-to-moderate OSA. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive a radiofrequency volumetric reduction of palatal tissues and base of tongue, the evidence includes two sham-controlled randomized trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Single-stage radiofrequency to palatal tissues did not improve outcomes compared with sham. Multiple sessions of radiofrequency to the palate and base of tongue did not significantly (statistically or clinically) improve AHI, and the improvement in functional outcomes was not clinically significant. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive palatal stiffening procedures, the evidence includes two sham-controlled randomized trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The two RCTs differed in their inclusion criteria, with the study that excluded patients with Friedman tongue position of IV and palate of 3.5 cm or longer reporting greater improvement in AHI (45% success) and snoring (change of -4.7 on a 10-point visual analog scale) than the second trial. Additional study is needed to corroborate the results of the more successful trial and, if successful, define the appropriate selection criteria. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive tongue base suspension, the evidence includes feasibility RCT with 17 patients. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT compared tongue suspension plus uvulopalatopharyngoplasty with tongue advancement plus uvulopalatopharyngoplasty and showed success rates of 50% to 57% for both procedures. RCTs with a larger number of subjects are needed to determine whether tongue suspension alone or added to uvulopalatopharyngoplasty improves the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive hypoglossal nerve stimulation, the evidence includes two nonrandomized studies with historical controls and prospective single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Hypoglossal nerve stimulation has shown success rates for about two-thirds of a subset of patients who met selection criteria that included AHI, body mass index, and favorable pattern of palatal collapse. These results were maintained out to five years in the pivotal single-arm study. Limitations of the published evidence preclude determining the effects of the technology on net health outcome. Evidence reported through clinical input supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Clinical input indicates that HNS leads to a meaningful improvement in health outcomes in appropriately selected adult patients with a favorable pattern of non-concentric palatal collapse. The alternative treatment for this anatomical endotype is maxillo-mandibular advancement (MMA), which is associated with greater morbidity and lower patient acceptance than HNS. The improvement in AHI with HNS, as shown in the STAR trial, is similar

to the improvement in AHI following MMA. Clinical input also supports that HNS results in a meaningful improvement in health outcomes in appropriately selected adolescents with OSA and Down's syndrome who have difficulty in using CPAP. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome for patients meeting the following selection criteria which are based on information from clinical study populations and clinical expert opinion.

- Age  $\geq 22$  years in adults or adolescents with Down's syndrome age 10 to 21; AND
- Diagnosed moderate to severe OSA (with less than 25% central apneas); AND
- CPAP failure or inability to tolerate CPAP; AND
- Body mass index  $\leq 32$  kg/m<sup>2</sup> in adults; AND
- Favorable pattern of palatal collapse

### 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 select 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 those patients who have:

- Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of 15 or more events per hour, or
- AHI or RDI of at least five events per hour with one or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or 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 those patients who have:

- AHI or RDI of 15 or more events per hour, or
- AHI or RDI of at least five events per hour with one or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or 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.

Hypoglossal nerve stimulation may be considered **medically necessary** in adults with OSA under the following conditions:

- Age 22 years or older; AND
- AHI of 15 or more with less than 25% central apneas; AND

- CPAP failure (residual AHI of 15 or more or failure to use CPAP four hours or more per night for five or more nights per week) or inability to tolerate CPAP; AND
- Body mass index is 32 kg/m<sup>2</sup> or less; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (see Policy Guidelines).

Hypoglossal nerve stimulation may be considered **medically necessary** in adolescents or young adults with Down syndrome and OSA under the following conditions:

- Age 10 to 21 years; AND
- AHI of more than 10 and less than 50 with less than 25% central apneas after prior adenotonsillectomy; AND
- Have either tracheotomy or be ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device; AND
- Body mass index 95<sup>th</sup> percentile or less for age; AND
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy (See Policy Guidelines).

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
- 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
- Tongue base suspension
- All other minimally-invasive surgical procedures not described above.

Implantable hypoglossal nerve stimulators are considered **investigational** for all indications, other than listed above.

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. A smaller number of patients may use oral appliances as a first-line treatment (see the Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome Protocol). 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 ten 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.

The hypoglossal nerve (cranial nerve XII) innervates the genioglossus muscle. Stimulation of the nerve causes anterior movement and stiffening of the tongue and dilation of the pharynx. Hypoglossal nerve stimulation reduces airway collapsibility and alleviates obstruction at both the level of the soft palate and tongue base.

Drug-induced sleep endoscopy (DISE) replicates sleep with an infusion of propofol. DISE will suggest either a flat, anterior-posterior collapse or complete circumferential oropharyngeal collapse. Concentric collapse decreases the success of hypoglossal nerve stimulation and is an exclusion criterion from the Food and Drug Administration.

## 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. 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. 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 associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

## REGULATORY STATUS

The regulatory status of minimally invasive surgical interventions is shown in Table 1.

Table 1. Minimally Invasive Surgical Interventions for Obstructive Sleep Apnea

Interventions	Devices (predicate or prior name)	Manufacturer (previously owner)	Indication	PMA/510(k)	Year	FDA Product Code
<b>LAUP</b>	<b>Various</b>					
Radiofrequency ablation	Somnoplasty®		Simple snoring and for the base of the tongue for OSA	K982717	1998	GEI
Palatal Implant	Pillar® Palatal Implant	Pillar Palatal (Restore Medical/Medtronic)	Stiffening the soft palate which may reduce the severity of snoring and incidence of airway obstructions in patients with mild-to-moderate OSA	K040417	2004	LRK
Tongue base suspension	AIRvance® (Repose)	Medtronic	OSA and/or snoring. The AIRvance™ Bone Screw System is also suitable for the performance of a hyoid suspension	K122391	1999	LRK

Interventions	Devices (predicate or prior name)	Manufacturer (previously owner)	Indication	PMA/510(k)	Year	FDA Product Code
	Encore™ (PRELUDE III)	Siesta Medical	Treatment of mild or moderate OSA and/or snoring	K111179	2011	ORY
Hypoglossal nerve stimulation	Inspire II Upper Airway Stimulation	Inspire Medical Systems	“a subset of patients with moderate to severe obstructive sleep apnea” (AHI ≥15 and ≤65) in adults ≥22 years who have failed (AHI >15 despite CPAP usage) or cannot tolerate (<4 h use per night for ≥5 nights per week) CPAP and do not have complete concentric collapse at the soft palate level. Failure includes unwillingness to use CPAP.	P130008 S021	2014 2017	MNQ
	aura6000®	ImThera Medical		IDE	2014	

AHI: Apnea/Hypopnea Index; CPAP: continuous positive airway pressure; IDE: investigational device exemption; LAUP: Laser-assisted uvulopalatoplasty; OSA: obstructive sleep apnea.

## 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 and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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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