

Protocol

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

(701101)

Medical Benefit		Effective Date: 04/01/21	Next Review Date: 09/23
Preauthorization	No	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, 01/19, 09/19, 01/20, 01/21, 09/21, 09/22	

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.

RELATED PROTOCOL

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

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 individuals who have failed conservative therapy, established surgical approaches may be indicated. This protocol 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 (HNS). This evidence review does not address conventional surgical procedures such as uvulopalatopharyngoplasty (UPPP), 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 that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive radiofrequency volumetric reduction of palatal tissues and base of tongue, the evidence includes 2 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 that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive palatal stiffening procedures, the evidence includes 2 sham-controlled randomized trials and several case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The 2 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 that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive tongue base suspension, the evidence includes a 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 UPPP with tongue advancement plus UPPP 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 UPPP improves the net health outcome. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive hypoglossal nerve stimulation, the evidence includes a systematic review, 1 RCT, nonrandomized prospective studies, nonrandomized studies with historical controls, and prospective single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A double-blind, multicenter RCT of 89 adults with moderate-to-severe OSA who did not tolerate continuous positive airway pressure (CPAP) found significant short-term improvement in AHI, Epworth Sleepiness Scale, and quality of life measures with HNS compared to sham stimulation. The study was limited by a short duration of follow-up and lack of diverse individuals included in the trial. 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 across nonrandomized trials. These results were maintained out to 5 years in the pivotal single-arm study. The single prospective comparative study of patients who received HNS versus patients who were denied insurance coverage for the procedure has a high potential for performance bias. For children and adolescents with OSA and Down Syndrome who are unable to tolerate CPAP, the evidence includes a safety study with 20 patients who were treated at tertiary care centers. The success rate was 70% with 2 adverse events of the leads, which were resolved with further surgery. A larger study of 42 individuals with Down Syndrome and OSA found a similar success rate of 73.2% with 4 device extrusions corrected with replacement surgery. Limitations of the current evidence base preclude determination of who is most likely to benefit from this invasive procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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/m² 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 95th 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 ten 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.

MEDICARE ADVANTAGE

An FDA-approved hypoglossal nerve neurostimulation may be considered **medically necessary** for the treatment of moderate to severe obstructive sleep apnea when ALL of the following criteria are met:

1. Age 22 years or older; and
2. Body mass index (BMI) is less than 35 kg/m²; and
3. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS IMPLANT; and
4. Has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); and
5. AHI is 15 to 65 events per hour; and
6. Has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than four hours per night, five nights per week or the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert; and
7. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; and
8. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

BACKGROUND

OBSTRUCTIVE SLEEP APNEA

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 individuals 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.

There are racial and ethnic health disparities seen for OSA, impacting the prevalence of disease and accessibility to treatment options, particularly affecting children. Black children are 4 to 6 times more likely to have OSA than white children.¹ Among young adults 26 years of age or younger, African American individuals are 88% more likely to have OSA compared to white individuals. Another study found that African American individuals 65 years of age and older were 2.1 times more likely to have severe OSA than white individuals of the same age group. These health disparities may affect accessibility to treatment for OSA and impact health outcomes. One analysis of insurance claims data, including over 500,000 patients with a diagnosis of OSA, found that increased age above the 18- to 29- year range ($p < .001$) and Black race ($p = .020$) were independently associated with a decreased likelihood of receiving surgery for sleep apnea.² Lee et al (2022) found that Black men had a continuous mortality increase specifically related to OSA over the study period (1999 to 2019; annual percentage change 2.7%; 95% confidence interval, 1.2 to 4.2) compared to any other racial group.³

TERMINOLOGY AND DIAGNOSTIC CRITERIA FOR OSA ARE SHOWN IN TABLE 1

Table 1. Terminology and Definitions for Obstructive Sleep Apnea

Terms	Definition
Respiratory event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by $\geq 90\%$ of the pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as ≥ 2 missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 3% or 4% decrease in arterial oxygen desaturation (depending on the scoring criteria) or arousal. Hypopneas in children are scored by a $\geq 50\%$ drop in nasal pressure and either a $\geq 3\%$ decrease in oxygen saturation or associated arousal.
RERA	Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea
Respiratory event reporting	
Apnea/Hypopnea Index (AHI)	The average number of apneas or hypopneas per hour of sleep
Respiratory Disturbance Index (RDI)	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
Respiratory event index (REI)	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available.
Diagnosis	
Obstructive sleep apnea (OSA)	Repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
Mild OSA	Adults: AHI or RDI of 5 to < 15 . In children: AHI ≥ 1 to < 5
Moderate OSA	Adults: AHI or RDI of 15 to < 30 ; Children: AHI of > 5 to 10
Severe OSA	Adults: AHI ≥ 30 . Children: AHI of > 10
Treatment	
Positive airway pressure (PAP)	Positive airway pressure may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure.
PAP failure	Usually defined as an AHI > 20 events per hour while using PAP
PAP intolerance	PAP use for less than 4 h per night for 5 nights or more per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA

OSA: obstructive sleep apnea; PSG: Polysomnographic

REGULATORY STATUS

The regulatory status of minimally invasive surgical interventions is shown in Table 2.

Table 2. 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
LAUP Radiofrequency ablation	Various 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
	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	Patients ≥18 years with AHI ≥15 and ≤65 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. Patients between ages 18 and 21 should also be contraindicated for or not effectively treated by adenotonsillectomy.	P130008 S039	2014	MNQ
	aura6000®	ImThera Medical		IDE	2014	
Hypoglossal nerve stimulation	Genio™	Nyxo		European CE Mark	2019	
Hypoglossal nerve stimulation	Apnex System®	Apnex				

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

The expanded indication for hypoglossal nerve stimulation in patients age 18 to 21 was based on patients with Down Syndrome and is contingent on a post-approval study of the Inspire® UAS in this age group. The post-approval study will be a multicenter, single-arm, prospective registry with 60 pediatric patients age 18 to 21. Visits will be scheduled at pre-implant, post-implant, six months, and yearly thereafter through five years.

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.**

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

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