

MEDICAL POLICY



SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS	EFFECTIVE DATE: 11/19/99 REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18
POLICY NUMBER: 7.01.41 CATEGORY: Technology Assessment	PAGE: 1 OF: 11
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

I. Nasal Surgery

Based upon our criteria and assessment of peer-reviewed literature, *Septoplasty, Turbinate Reduction,* and *Polypectomy* do not improve patient outcomes and are **not medically necessary** for obstructive sleep apnea (OSA). However, nasal surgery is considered **medically appropriate** to correct a nasal obstruction that prohibits the use of CPAP/BiPAP.

II. Upper Airway Surgery

- A. *Palatopharyngoplasty* (eg, uvulopalatopharyngoplasty(UPPP), uvulopharyngoplasty): Based upon our criteria and assessment of the peer-reviewed literature, UPPP, with or without inferior sagittal osteotomy (ISO) with hyoid suspension, for the treatment of OSA has been medically proven to be effective and therefore **medically appropriate** for the following indications:
(*Must meet criteria 1 AND 3 OR 2 AND 3*)
1. Documented OSA with an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of 15 or greater events per hour regardless of symptoms; OR
 2. Documented OSA with an AHI or RDI of 5 to 14 events per hour accompanied by symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, or documented cardiovascular diseases, including hypertension and ischemic heart disease;
- AND
3. Failure of all forms of medical management of OSA, including documented intolerance to positive airway pressure (e.g., CPAP, BiPAP).
- B. *Radiofrequency ablation* or *Somnoplasty of palatal tissues*: Based upon our criteria and assessment of the peer-reviewed literature, Somnoplasty does not improve patient outcomes and is **not medically necessary** for the treatment of OSA.
- C. *Laser-assisted Uvulopalatoplasty (LAUP)*: Based upon our criteria and assessment of the peer-reviewed literature, LAUP does not improve patient outcomes and is **not medically necessary** for the treatment of OSA.
- D. *Expansion sphincter pharyngoplasty/expansion sphincteroplasty (ESP)*: Based upon our criteria and lack of the peer-reviewed literature, ESP has not been proven medically effective and is considered **investigational**.
- E. *Tonsillectomy and adenoidectomy (T&A)*: Based upon our criteria and assessment of the peer-reviewed literature, tonsillectomy and adenoidectomy has been medically proven to be effective and therefore **medically appropriate** for the treatment of OSA. T&A is also considered **medically appropriate** to correct an upper airway obstruction that prohibits the use of CPAP/BiPAP.
- F. *Injection Snoreplasty*: Based upon our criteria and assessment of peer-reviewed literature, injection snoreplasty has not been medically proven to be effective and is considered **investigational** for the treatment of OSA. Injection Snoreplasty for the treatment of snoring alone is considered **not medically necessary**.

<p>SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS</p> <p>POLICY NUMBER: 7.01.41</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18</p> <p>PAGE: 2 OF: 11</p>
--	--

- G. *Cautery-Assisted Palatal Stiffening Operation (CAPSO)*: Based upon our criteria and assessment of peer-reviewed literature, cautery-assisted palatal stiffening has not been medically proven to be effective and is considered **investigational** for the treatment of OSA. CAPSO for the treatment of snoring alone is considered **not medically necessary**.
- H. *Palatal Implant System (e.g., Pillar™ Palatal Implant)*: Based upon our criteria and assessment of peer-reviewed literature, the palatal implant system has not been medically proven to be effective and is considered **investigational** for the treatment of OSA. This implant as a treatment of snoring alone is considered **not medically necessary**.

III. Lower Airway Surgery

- A. *Jaw realignment Surgery* (e.g., inferior sagittal mandibular osteotomy, genioglossal advancement, hyoid myotomy and suspension, maxillomandibular osteotomy and advancement): Based upon our criteria and assessment of the peer-reviewed literature, jaw realignment surgery has been medically proven to be effective and therefore **medically appropriate** for the treatment of OSA in patients who meet the criteria for UPPP, as stated in Policy Statement II A.
- B. *Tongue suspension suture system (e.g., Airvance® [formerly known as the Repose™ System], Encore™ System)*: Based upon our criteria and assessment of peer-reviewed literature, tongue suspension suture systems have not been medically proven to be effective and are considered **investigational** for the treatment of OSA.
- C. *Radiofrequency ablation or Somnoplasty of the base of the tongue*: Based upon our criteria and assessment of the peer-reviewed literature, Somnoplasty does not improve patient outcomes and is **not medically necessary** for the treatment of OSA.

IV. Surgical Bypass of the Airway

Tracheostomy: Based upon our criteria and assessment of the peer-reviewed literature, tracheostomy has been medically proven to be effective and therefore, **medically appropriate** for treatment of severe, life-threatening OSA.

V. Hypoglossal Nerve/Upper Airway Stimulation (e.g., Inspire II Upper Airway Stimulation system)

Based upon our criteria and the lack of peer-reviewed literature, the use of implantable hypoglossal nerve stimulation is considered **investigational** in the treatment of OSA.

VI. Cardiac Pacing

Atrial overdrive pacing: Based upon our criteria and assessment of peer-reviewed literature, atrial overdrive pacing is considered **investigational** as a treatment of OSA.

VII. Based upon our criteria and assessment of peer-reviewed literature, treatment for snoring without polysomnographic evidence of OSA does not improve patient outcomes and is **not medically necessary**.

Refer to Corporate Medical Policy #1.01.06 regarding Positive Pressure Airway Devices.

Refer to Corporate Medical Policy#1.01.07 regarding Oral Appliances for the Treatment of Sleep-Related Breathing Disorders.

Refer to Corporate Medical Policy #2.01.28 regarding Sleep Studies.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

Refer to Corporate Medical Policy #7.01.05 Vagus Nerve Stimulation for vagus nerve stimulators used for other indications than Hypoglossal stimulation.

<p>SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS</p> <p>POLICY NUMBER: 7.01.41 CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99 REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18</p> <p>PAGE: 3 OF: 11</p>
--	--

POLICY GUIDELINES:

- I. Surgery is not the first treatment of choice for OSA. It is reserved for patients who have failed all forms of medical management of OSA, or are intolerant of CPAP and BiPAP, and/or oral appliances.
- II. In severe OSA disease, surgery may not be curative and follow-up studies may be warranted post-operatively.
- III. For those patients who have been found to have multiple levels or anatomical sites of obstructive sleep apnea (e.g., hypopharyngeal, retropalatal, and/or retrolingual) on clinical evaluation, a simultaneous combination of surgical procedures may be appropriate for the best surgical outcome and to minimize operative risk. Nasal surgery is not considered part of a multilevel surgery to correct OSA. If a nasal obstruction precludes the use of CPAP, then nasal surgery to allow the use of CPAP should be performed first.
- IV. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Obstructive sleep apnea (OSA) is the cessation of airflow through the nose and mouth for at least 10 seconds with a respiratory effort noted, and is usually associated with a reduction in blood oxygen saturation. Features of OSA include daytime somnolence, disordered sleep, and a variety of clinical symptoms. It is also common to find decreased motor and perceptual skills while awake, which correlate with the severity of hypoxia during sleep. The syndrome is most common in middle-aged, obese, male smokers.

In patients with OSA, the normal pharyngeal narrowing is accentuated by anatomic factors, such as a short neck, elongated palate and uvula, or large tonsillar pillars with redundant lateral pharyngeal wall mucosa. OSA may also be associated with a wide variety of craniofacial abnormalities, including micrognathia, retrognathia or maxillary hypoplasia.

When patients with OSA are not able achieve benefit with non-invasive positive pressure therapy (PAP) or fail the gold standard of treatment in the form of continuous positive airway pressure (CPAP) a second-line treatment may be a surgical option. The AASM proposes the use of specific guidelines such as CPAP adherence for at least 4 hours of sleep for at least 70% of the days or an improvement in clinical symptoms. The Food and Drug Administration (FDA) defines failed compliance as using the CPAP less than 4 hours a night for less than 5 nights per week. Not all patients may be candidates for surgical options for appropriate polysomnographic, age, BMI and objective upper airway evaluation measures may be required for proper patient selection.

The goal of surgery is to enlarge the airway and prevent airway collapse and oxygen desaturation to prevent the clinical symptoms of OSA: excessive daytime sleepiness, impaired cognition, and mood disorders. Surgery is site specific, performed to enlarge a certain portion of the airway.

I. Nasal Surgery

- A. *Septoplasty* corrects a deviated septum, which may obstruct the nasal airway.
- B. *Turbinates Reduction* reduces the size of one of the 3 turbinates in each nostril, which can improve the size of the nasal airway. The surgery may be performed with lasers, cautery or radiofrequency ablation.
- C. *Polypectomy* removes nasal polyps, which obstruct the nasal airways.

<p>SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS</p> <p>POLICY NUMBER: 7.01.41</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18</p> <p>PAGE: 4 OF: 11</p>
--	--

II. Upper Airway Surgery

- A. *Uvulopalatopharyngoplasty (UPPP)* removes the uvula and the lower edge of the soft palate is trimmed. The surgery may include several technical variations. All techniques include the basic UPPP procedure, but often additional surgery is performed, such as tonsillectomy. UPPP with inferior sagittal osteotomy with hyoid suspension is one variation proposed to improve the surgical outcome.
- B. *Radio-frequency ablation* of soft palate tissue, or *Somnoplasty System*, uses a device comprised of an electrosurgical (RF) generator and tissue coagulating electrodes, which ablate soft tissues in the palate or uvula.
- C. *Laser-Assisted Uvulopalatoplasty (LAUP)* involves the progressive removal of the back edge of the palate and a reduction in the size of the uvula. It is most frequently performed with a carbon dioxide laser and is typically performed over several surgical sessions in an outpatient setting.
- D. *Expansion sphincter pharyngoplasty/expansion sphincteroplasty (ESP)* is a modification of a UPPP in which the lateral pharyngeal wall is stiffened in order to prevent collapse. ESP consists of a tonsillectomy, expansion pharyngoplasty, rotation of the palatopharyngeus muscle, partial uvulectomy, and closure of the anterior and posterior tonsillar pillars.
- E. *Tonsillectomy and Adenoidectomy*. Enlarged tonsils may narrow the width of the upper airway; the adenoids are at the back of the nose and may obstruct the nasal airway. Removal of tonsils and adenoids are performed most often in children with sleep apnea. Adenoids usually shrink with age and only rarely require removal in adults.
- F. *Injection Snoreplasty* involves the injection of a sclerosing agent (tetradecyl Sulfate/Sotradecol) into the soft palate, which causes scarring and subsequent stiffening of the soft palate. This is thought to reduce the flutter of the soft palate, which is the cause of primary snoring.
- G. *Cautery-Assisted Palatal Stiffening Operation (CAPSO)* is a procedure where electrocautery is utilized to remove a portion of the soft palate and uvula. It is carried out under local anesthesia, on an outpatient basis.
- H. *Palatal Implant System* involves insertion of three narrow bands of braided polyester under the skin of the soft palate using a delivery tool. The implant has been proposed for the treatment of snoring and for the treatment of palate-related mild to moderate sleep apnea. Once in place, the implants stiffen the palate by mechanical means in addition to inducing a fibrotic response that encapsulates and secures the implants, further stiffening the palatal tissue. Palatal implants, though designed to be permanent, are removable. Implantation is carried out under local anesthesia.

III. Lower Airway Surgery

- A. *Jaw realignment Surgery* (e.g., inferior sagittal mandibular osteotomy, genioglossal advancement, hyoid myotomy and suspension, maxillomandibular osteotomy and advancement) is a more aggressive surgical procedure than UPPP. It has been used to relieve obstruction in OSA patients who meet the criteria for UPPP.
- B. A *tongue suspension suture system* (e.g., Airvance® [formerly known as the Repose™ System], Encore™ System) involves preventing the tongue from falling back during sleep. The Airvance® System uses a titanium screw in the chin attached to a permanent stitch through the tongue to pull it forward. The Encore™ System is similar to the Airvance® System but creates a suture loop within the tongue without having to create penetrations through the mucosal surface of the tongue.
- C. *Radiofrequency ablation*, or *Somnoplasty System*, uses a device, which is comprised of an electrosurgical (RF) generator and tissue coagulating electrodes that ablate soft tissues, creating volumetric tissue reduction of the tongue.

<p>SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS</p> <p>POLICY NUMBER: 7.01.41</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18</p> <p>PAGE: 5 OF: 11</p>
--	--

IV. Surgical Bypass of the Airway

A *tracheostomy* bypasses the narrow segments of the airway that cause obstruction and create an opening in the neck that allows the patient to breathe unobstructed at night. This is done in severe, life-threatening cases of sleep apnea.

V. Hypoglossal Nerve/Upper Airway Stimulation

Electrical stimulation of the hypoglossal nerve has been proposed as a method to maintain upper airway patency by augmenting tone to the upper airway. The implant device consists of a pulse generator, a stimulation lead, and a sensing lead and is designed to detect the patient's respiratory effort and maintain airway patency with mild stimulation of the hypoglossal nerve. Therapy settings are stored in the pulse generator and configured by the physician using an external programmer. The patient uses a remote to turn therapy on before they go to sleep and to turn therapy off when they wake up. The sleep remote also provides the ability to pause therapy and adjust stimulation amplitude within physician defined limits.

On April 30, 2014, the U.S. Food and Drug Administrations (FDA) granted pre-market approval for *the Inspire® Upper Airway Stimulation (UAS) system (Inspire Medical Systems)* for use in treating a subset of patients, age 22 years and older, with moderate to severe obstructive sleep apnea (apnea-hypopnea index [AHI] of 20 to 65) who have failed or cannot tolerate positive airway pressure (PAP) treatments and who do not have a complete concentric collapse, as seen during drug induced sleep endoscopy, at the soft palate level. Body Mass Index (BMI) greater than 32 was not studied as part of the pivotal trial. Based on data from the feasibility study, it may be associated with decreased likelihood of response to treatment. *Use of Inspire UAS in higher BMI (>32) patients is not recommended due to unknown effectiveness and safety.* Other devices under investigation include, but may not be limited to, the Aura™ 6000 System (Imthera Medical) and the HGNS® System (Apnex Medical).

VI. Atrial overdrive pacing

It has been found that bradycardia frequently occurs during episodes of apnea. Therefore, atrial overdrive pacing after implantation of a pacemaker has been proposed as a treatment to reduce the incidence of obstructive sleep apnea events.

RATIONALE:

Obstructive sleep apnea has been associated with significant co-morbidities. The gold standard of treatment has been non-invasive ventilation in the form of continuous positive airway pressure (CPAP). When anatomical obstructions exist, surgical intervention is used. The anatomical location for obstruction can occur at several different locations along the airway and, in specific circumstances, combined surgical procedures can offer a higher overall success rate than one single procedure alone. Because of the complexity of airway narrowing or collapse during sleep, any one surgical procedure may not eradicate the patient's sleep apnea. Though procedures such as septoplasty, nasal turbinectomies or nasal polypectomies may be indicated for correction of a nasal airway obstruction, their role in treating multilevel OSA is very limited.

LAUP studies have shown that a large proportion of patients developed significant worsening of objective sleep parameters postoperatively. There are no data regarding the long-term efficacy and safety of *injection snoreplasty* as a treatment for OSA. The scientific evidence is insufficient to permit conclusions concerning the effect of *CAPSO* on health outcomes. *Somnoplasty* has been approved by the FDA only as a treatment for snoring. Current literature regarding radio-frequency/ *somnoplasty* does not support the efficacy or applicability of this procedure for OSA. Studies also fail to report long-term outcomes or recurrence rates.

There is insufficient evidence to support the safety and efficacy of the use of the *Repose™ tongue suspension system* in the treatment of OSA. Although preliminary studies have shown subjective improvements in snoring and decreases in the mean RDI, the overall surgical cure rate was only 20% (Miller, et al. 2002). Kuhnel, et al (2005) investigated the efficacy of tongue base suspension in modifying the posterior airway space in patients with OSA. The posterior airway

<p>SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS</p> <p>POLICY NUMBER: 7.01.41</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18</p> <p>PAGE: 6 OF: 11</p>
--	--

space was widened by at least 2 mm in 60% of cases. Daytime sleepiness improved subjectively in 67% of patients, and the respiratory disturbance index improved postoperatively in 55%. The correlation between posterior airway space widening and the improvements in daytime sleepiness and respiratory disturbance index was not significant. The authors concluded that surgical intervention in obstructive sleep apnea syndrome with the Repose System does not result in permanent anatomical change in the posterior airway space.

The *Pillar™ Palatal Implant* received FDA approval for the treatment of snoring in 2003 and subsequently, FDA approval as a treatment of OSA in September 2004. There is insufficient peer-reviewed evidence to support use of the Pillar implant as a treatment of OSA. The literature mainly consists of small case series investigating its use for snoring. Studies with OSA patients had very small sample sizes with limited follow-up and were vendor sponsored (Nordgard, et al. 2006; Friedman, et al. 2006).

Many patients with OSA also suffer from nocturnal bradycardia or tachyarrhythmias. It has been observed that in some patients, the use of a pacemaker to increase the heart rate and cardiac function during sleep could also reduce the incidence of apneic episodes. Although a clinical study by Garrigue, et al (2002) found that *atrial overdrive pacing* significantly reduced the number of episodes of central and obstructive sleep apnea, these positive findings have not been validated in any of the newer, well-designed studies. Atrial overdrive pacing has not been found to reduce the number of hypopnea- apnea events in patients with OSA (Krahn, et al. 2006; Unterberg, et al. 2005; Luthje, et al. 2005; Simantirakis, et al. 2005; Pepin et al. 2005).

Hypoglossal Nerve/Upper Airway Stimulation. In 2014, the STAR Trial Group (Funded by Inspire Medical Systems) the reported 12-month outcomes from a multicenter single-arm study of 126 patients implanted with the Inspire® Upper Airway Stimulation system. Patients were included if the apnea hypopnea index (AHI) score from the screening polysomnogram (PSG) was at least 20 and no more than 50 events per hour. At 12 months after implantation 66% of the participants met the co-primary outcome of at least a 50% decrease in AHI with a final AHI of less than 20 events per hour and 75% met the co-primary outcome of a reduction in the oxygen desaturation index score of 25% or more. The median AHI decreased from 29.3 to 9.0 events per hour and the oxygen desaturation index score (ODI, number of times per hour that SO2 drops by 4% or more) decreased from 25.4 to 7.4 events per hour. The mean Epworth Sleepiness Scale (ESS) decreased from 11.6 to 7.0. The first 46 patients who responded to therapy were then randomized to either continued therapy or withdrawal from therapy. After 7 days, AHI of the continued treatment group remained stable from a mean of 7.2 to 8.9 events per hour, whereas the mean AHI in the withdrawal group increased from 7.6 to 25.8. Eighteen percent of participants had temporary tongue weakness and 21% reported tongue soreness, including abrasion, which resulted from stimulation-induced tongue motion over the lower teeth. (Strollo, et al). Two participants experienced serious adverse events associated with the device. The lack of a control group limits the validity of the results of this study. This study was funded by Inspire Medical in which there was only a 12 month follow up and they concluded that while HGNS demonstrated favorable safety, feasibility and efficacy and HNS may be a viable treatment option in OSA HNS it does not alleviate OSA in all subjects and there were no long term outcomes. This study is not adequate enough to approve implantable hypoglossal nerve stimulation.

In an editorial referencing the issue of the *New England Journal of Medicine* by Strollo et al, Malhotra acknowledged that the STAR study had many limitations. The population studied were carefully selected, and only a minority of screened patients underwent implantation. Second, some residual disease were seen during the therapy, as shown by a score on the apnea-hypopnea index (the number of apneas plus hypopneas per hour of sleep) of 9.0 events per hour at 12 months, leading to an interpretation that obstructive sleep apnea was reduced but not eliminated by hypoglossal nerve stimulation. The experimental design was an unblinded, prospective, open-label study, without a concomitant control group. Diet, exercise, or other unmeasured factors may have changed during the course of the study and could have contributed to the observed reduction in obstructive sleep apnea.

A series of 31 patients implanted with the Apnex hypoglossal nerve stimulation system (HGNS®) was reported in 2014. There was a significant improvement (p less than 0.001) from baseline to 12 months in AHI (45.4±17.5 to 25.3±20.6

<p>SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS</p> <p>POLICY NUMBER: 7.01.41</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18</p> <p>PAGE: 8 OF: 11</p>
--	--

ICD10:	F51.8	Other sleep disorders not due to a substance or known physiological condition
	G47.00	Insomnia, unspecified
	G47.10	Hypersomnia, unspecified
	G47.20	Circadian rhythm sleep disorder, unspecified type
	G47.30-G47.39	Sleep apnea (code range)
	G47.69	Other sleep related movement disorders
	G47.8-G47.9	Other and unspecified sleep disorders (code range)

REFERENCES:

American Academy of Otolaryngology – Head and Neck Surgery. Nasal surgery and OSAS. Position statement. Revised 2012 Dec 8, Updated 7/31/14 [<http://www.entnet.org/node/548>] accessed 3/27/18.

American Academy of Otolaryngology – Head and Neck Surgery. Surgical management of obstructive sleep apnea. Position statement. Revised 2014 Mar 2 [<http://www.entnet.org/content/surgical-management-obstructive-sleep-apnea>] accessed ~~3/20/17~~ 3/27/18.

American Academy of Otolaryngology – Head and Neck Surgery. Uvulopalatopharyngoplasty. Position statement. Reaffirmed 2012 Dec 8 [<http://www.entnet.org/node/896>] accessed 3/27/18.

American Academy of Otolaryngology – Head and Neck Surgery. Tongue suspension. Position statement. 2012 Dec 8 [<http://www.entnet.org/node/399>] accessed 3/27/18.

American Academy of Otolaryngology-Head and Neck Surgery. 2016 Position Statement: Hypoglossal Nerve Stimulation for Treatment of Obstructive Sleep Apnea (OSA) <http://www.entnet.org/content/position-statement-hypoglossal-nerve-stimulation-treatment-obstructive-sleep-apnea-osa>. Accessed 3/27/18.

*American Academy of Sleep Medicine. Practice parameters for the use of laser-assisted uvulopalatoplasty. An update for 2000. 2001 Aug [http://www.aasmnet.org/Resources/PracticeParameters/PP_Uvulopalatoplasty.pdf] accessed 3/27/18.

*Aurora RN, et al. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. Sleep 2010 Oct 1;33(10):1408-13 [http://www.aasmnet.org/Resources/PracticeParameters/PP_SurgicalModificationsOSA.pdf] accessed 3/27/18.

*Baldassari CM, et al. Changes in central apnea index following pediatric adenotonsillectomy. Otolaryngol Head Neck Surg 2012 Mar;146(3):487-90.

*BlueCross BlueShield Association. Surgical management of obstructive sleep apnea syndrome/upper airway resistance syndrome - Archived. Medical Policy Reference Manual Policy #7.01.51. 2010 Apr 8.

BlueCross BlueShield Association. Surgical treatment of snoring and obstructive sleep apnea syndrome. Medical Policy Reference Manual Policy # 7.01.101. 2017 Sept 14.

*BlueCross BlueShield Association Technology Evaluation Center (TEC). Radiofrequency volumetric tissue reduction for sleep-related breathing disorders. 2000 Dec;15(15).

Browaldh N, et al. SKUP3 randomised controlled trial: polysomnographic results after uvulopalatopharyngoplasty in selected patients with obstructive sleep apnoea. Thorax 2013 Sep;68(9):846-53.

Calik MW. Treatments for Obstructive Sleep Apnea. J Clin Outcomes Manag. 2016 Apr;23(4):181-192

<p>SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS</p> <p>POLICY NUMBER: 7.01.41</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18</p> <p>PAGE: 9 OF: 11</p>
--	--

Camacho M, et al. Tracheostomy as treatment for adult obstructive sleep apnea: a systematic review and meta-analysis. Laryngoscope 2014 Mar;124(3):803-11.

Camacho M, et al. The effect of nasal surgery on continuous positive airway pressure device use and therapeutic treatment pressures: a systematic review and meta-analysis. Sleep 2015 Feb 1;38(2):279-86.

Certal VF, et al. Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: A systematic review and meta-analysis. Laryngoscope 2014 Nov 12 [epub ahead of print].

Choi JH, et al. Efficacy of the Pillar implant in the treatment of snoring and mild-to-moderate obstructive sleep apnea: a meta-analysis. Laryngoscope 2013 Jan;123(1):269-76.

Choi JH, et al. Palatal implants for persistent snoring and mild obstructive sleep apnea after laser-assisted uvulopalatoplasty. Clin Exp Otorhinolaryngol. 2014 Mar;7(1):66-8.

*Epstein LJ, et al; Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. J Clin Sleep Med 2009 Jun 15;5(3):263-76.

Friedman M, et al. Targeted hypoglossal nerve stimulation for the treatment of obstructive sleep apnea: Six-month results. Laryngoscope. 2016 Nov;126(11):2618-2623.

*Garetz SL, et al. Quality of life and obstructive sleep apnea symptoms after pediatric adenotonsillectomy. Pediatrics 2015 Feb;135(2):e477-86.

*Garrigue S, et al. Benefit of atrial pacing in sleep apnea syndrome. NEJM 2002 Feb 7;346(6):404-12.

Gillespie MB, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Patient-Reported Outcomes after 48 Months of Follow-up. Otolaryngol Head Neck Surg. 2017 Feb 1:194599817691491.

Goktas O, et al. Long-term results in obstructive sleep apnea syndrome (OSAS) after laser-assisted uvulopalatoplasty (LAUP). PLoS One. 2014 Jun 30;9(6):e100211.

Handler E, et al. Tongue suspension: an evidence-based review and comparison to hypopharyngeal surgery for OSA. Laryngoscope 2014 Jan;124(1):329-36.

*Holmlund T, et al. Effects of radiofrequency versus sham surgery of the soft palate on daytime sleepiness. Laryngoscope 2014 Oct;124(10):2422-6.

Ishii L, et al. Does nasal surgery improve OSA in patients with nasal obstruction and OSA? A meta-analysis. Otolaryngol Head Neck Surg 2015 Sep;153(3):326-33.

Kapur VK, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017 Mar 15;13(3):479-504.

Kezirian EJ, et al. Hypoglossal nerve stimulation improves obstructive sleep apnea: 12-month outcomes. J Sleep Res 2014 Feb;23(1):77-83.

*Krahn AD, et al. Physiologic pacing in patients with obstructive sleep apnea: a prospective, randomized crossover trial. J Am Coll Cardiol 2006 Jan 17;47(2):379-83.

*Lim J, et al. Adenotonsillectomy for obstructive sleep apnoea in children. The Cochrane Library. 2009 Issue 2, No. CD003136.

*Luthje L, et al. Atrial overdrive pacing in patients with sleep apnea with implanted pacemaker. Am J Respir Crit Care Med 2005 Jul 1;172(1):118-22.

Malhotra , et al. Hypoglossal-Nerve Stimulation for Obstructive Sleep Apnea. N Engl J Med. 2014 Jan 9;370(2):170-1.

<p>SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS</p> <p>POLICY NUMBER: 7.01.41</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18</p> <p>PAGE: 10 OF: 11</p>
--	---

Marcus CL, et al; Childhood Adenotonsillectomy Trial (CHAT). A randomized trial of adenotonsillectomy for childhood sleep apnea. N Engl J Med 2013 Jun 20;368(25):2366-76.

*Marcus CL, et al; American Academy of Pediatrics. Diagnosis and management of childhood obstructive sleep apnea syndrome. Technical report. Pediatrics 2012 Sep;130(3):e714-55.

Marcus CL, et al; American Academy of Pediatrics. Diagnosis and management of childhood obstructive sleep apnea syndrome. Clinical practice guideline. Pediatrics 2012 Sep;130(3):576-84.

*Miller FR, et al. Role of the tongue base suspension suture with the Repose System bone screw in the multilevel surgical management of obstructive sleep apnea. Otolaryngol Head Neck Surg 2002 Apr;126(4):392-8.

Murphey AW, et al. The effect of glossectomy for obstructive sleep apnea: a systematic review and meta-analysis. Otolaryngol Head Neck Surg 2015 Sep;153(3):334-42.

*Nordgard S, et al. Soft palate implants for the treatment of mild to moderate obstructive sleep apnea. Otolaryngol Head Neck Surg 2006 Apr;134(4):565-70.

Pavelec V, et al. A novel implantable device for the treatment of obstructive sleep apnea: clinical safety and feasibility. Nat Sci Sleep. 2016 May 4;8:137-44

Pengo MF, et al. Emerging technology: electrical stimulation in obstructive sleep apnea. J Thorac Dis. 2015 Aug;7(8):1286-97.

*Pepin JL, et al. Overdrive atrial pacing does not improve obstructive sleep apnoea syndrome. Eur Resp J 2005 Feb;25(2):343-7.

Pirklbauer K, et al. Maxillomandibular advancement for treatment of obstructive sleep apnea syndrome: a systematic review. J Oral Maxillofac Surg 2011 Jun;69(6):e165-76.

Rotenberg BW, et al. Trends in CPAP adherence over twenty years of data collection: a flattened curve. J Otolaryngol Head Neck Surg. 2016 Aug 19;45(1):43.

Sharafkhaneh A, et al. Effect of atrial overdrive pacing on obstructive sleep apnea in patients with systolic heart failure. Sleep Med. 2007 Jan;8(1):31-6.

*Simantirakis EN, et al. Atrial overdrive pacing for obstructive sleep apnea-hypopnea syndrome. NEJM 2005 Dec 15;353(24):2568-77.

Sommer UJ, et al. Tonsillectomy with Uvulopalatopharyngoplasty in Obstructive Sleep Apnea. Dtsch Arztebl Int. 2016 Jan 11;113(1-02):1-8.

Strollo PJ Jr, et al; STAR Trial Group. Upper-airway stimulation for obstructive sleep apnea. N Engl J Med 2014 Jan 9;370(2):139-49.

Tanna N, et al. Surgical Management of Obstructive Sleep Apnea. Plast Reconstr Surg. 2016 Apr;137(4):1263-72.

*Unterberg C, et al. Atrial overdrive pacing compared to CPAP in patients with obstructive sleep apnoea syndrome. Eur Heart J 2005 Dec;26(23):2568-75.

Vishesh KK, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017 Mar 15; 13(3): 479–504.

Woodson BT, et al; STAR Trial Investigators. Randomized controlled withdrawal study of upper airway stimulation on OSA: short- and long-term effect. Otolaryngol Head Neck Surg 2014 Nov;151(5):880-7.

*key article

SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS	EFFECTIVE DATE: 11/19/99
POLICY NUMBER: 7.01.41	REVISED DATE: 03/21/02, 02/20/03, 12/18/03, 01/20/05, 10/20/05, 09/21/06, 07/19/07, 05/14/08, 03/19/09, 03/18/10, 04/21/11, 03/15/12, 03/21/13, 03/20/14, 05/28/15, 03/17/16, 04/20/17, 04/19/18
CATEGORY: Technology Assessment	PAGE: 11 OF: 11

KEY WORDS:

Airvance®, Atrial overdrive pacing, Aura6000 System, CAPSO, Encore™, HGNS®, Hypoglossal Nerve Stimulation, Inspire II Upper Airway Stimulation System, LAUP, Pillar™, Repose™, Snoreplasty, Somnoplasty, UPPP.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Neither a National nor a Regional Medicare coverage determination addressing surgical management of obstructive sleep apnea has been identified.