# MEDICAL POLICY

Excellus

| SUBJECT: SURGICAL MANAGEMENT OF SLEEP DISORDERS | EFFECTIVE DATE: 11/19/99<br>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 |
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| POLICY NUMBER: 7.01.41<br>CATEGORY: Technology Assessment | PAGE: 1 OF: 7 |

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

## 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. *Uvulopalatopharyngoplasty (UPPP):* 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 a respiratory disturbance index (RDI) of 30 or greater events per hour regardless of symptoms; OR
2. Documented OSA with an RDI of 5 to 29 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 continuous positive airway pressure (CPAP) or 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. *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.

E. *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**.

F. *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**.

G. *Palatal Implant System:* 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 have failed UPPP.

B. *Repose™ tongue suspension system:* Based upon our criteria and assessment of peer-reviewed literature, the Repose™ System has not been medically proven to be effective and is 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. **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.

VI. 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.*

## 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.

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. *Turbinate 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.

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. *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.

E. *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.

F. *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.

G. *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 incapsulates 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 have not responded to UPPP.

B. A *tongue suspension suture*, or *Repose™ System*, involves preventing the tongue from falling back during sleep. The Repose™ System uses a titanium screw in the chin attached to a permanent stitch through the tongue to pull it forward.

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.

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. **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. 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 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).

**CODES:** Number Description

*Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

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| **CPT:** | 21141-21155, 21193-21206, 21244 | Jaw realignment surgery (code ranges) |
| | 31600 | Tracheostomy, planned (separate procedure) |
| | 41512 **(E/I)** | Tongue base suspension, permanent suture technique |
| | 41530 **(NMN)** | Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session |
| | 42145 | Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty) |
| | 42820 | Tonsillectomy and adenoidectomy; younger than age 12 |
| | 42821 | age 12 or over |



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| **HCPCS:** | C9727 **(E/I)** | Insertion of implants into soft palate; minimum of three implants |
| | S2080 **(NMN)** | Laser-assisted uvulopalatoplasty (LAUP) |
| **ICD9:** | 327.2-327.29 | Organic sleep apnea (code range) |
| | 780.50-780.59 | Sleep disturbances (code range) |
| **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 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 2/14/14.

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 2/14/14.

Bäck LJ, et al. Radiofrequency ablation treatment of soft palate for patients with snoring: a systematic review of effectiveness and adverse effects. Laryngoscope 2009 Jun;119(6):1241-50.

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

Baranchuk A, et al. Atrial overdrive pacing in sleep apnoea: a meta-analysis. Europace 2009 Aug;11(8):1037-40.

Bhattacharjee R, et al. Adenotonsillectomy outcomes in treatment of obstructive sleep apnea in children: a multicenter retrospective study. Am J Respir Crit Care Med 2010 Sep 1;182(5):676-83.

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. 2013 May 9.

*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.

Caples SM, et al. Surgical modifications of the upper airway for obstructive sleep apnea in adults: a systematic review and meta-analysis. Sleep 2010 Oct 1;33(10):1396-407.

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.

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. Updated systematic review of tonsillectomy and adenoidectomy for treatment of pediatric obstructive sleep apnea/hypopnea syndrome. Otolaryngol Head Neck Surg 2009 Jun;140(6):800-8.

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

Holty JE and Guilleminault C. Maxillomandibular advancement for the treatment of obstructive sleep apnea: a systematic review and meta-analysis. Sleep Med Rev 2010 Oct;14(5):287-97.

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

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.

Maurer JT. Surgical treatment of obstructive sleep apnea: standard and emerging techniques. Curr Opin Pulm Med 2010 Nov;16(6):552-8.

*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.

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.

Sinha AM, et al. Long-term effects of dynamic atrial overdrive pacing on sleep-related breathing disorders in pacemaker or cardioverter defibrillator recipients. Pacing Clin Electrophysiol 2009 Mar;32 Suppl 1:S219-22.

*Sundaram S, et al. Surgery for obstructive sleep apnea. Cochrane Database Syst Rev 2005 Oct 19;(4):CD001004.

Verse T and Hörmann K. The surgical treatment of sleep-related upper airway obstruction. Dtsch Arztebl Int 2011 Apr;108(13):216-21.

*Walker-Engstrom ML, et al. 4-year follow-up of treatment with dental appliance or uvulopalatopharyngoplasty in patients with obstructive sleep apnea: a randomized study. Chest 2002 Mar;121(3):739-46.

Weng CL, et al. A meta-analysis of the effects of atrial overdrive pacing on sleep apnea syndrome. Pacing Clin Electrophysiol 2009 Nov;32(11):1434-43.

*key article

**KEY WORDS:**

Atrial overdrive pacing, CAPSO, 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.