

Medical Coverage Policy | Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome



EFFECTIVE DATE: 03|01|2017
POLICY LAST UPDATED: 12|18|2018

OVERVIEW

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This policy addresses the various surgical procedures that have been evaluated for the treatment of adult and pediatric patients with OSA.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

The following minimally invasive surgical procedures are not covered for the sole or adjunctive treatment of OSA or upper airway resistance syndrome (UARS) as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Radiofrequency volumetric tissue reduction of the tongue, with or without radiofrequency reduction of the palatal tissues
- Laser-assisted uvulopalatoplasty (LAUP) or radiofrequency volumetric tissue reduction of the palatal tissues
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants
- Tongue base suspension
- All other minimally invasive surgical procedures not described above

Implantable hypoglossal nerve stimulators are considered not medically necessary for all indications, including but not limited to the treatment of OSA as the evidence is insufficient to determine the effects of the technology on health outcomes.

All interventions, including LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, are considered not medically necessary for the treatment of snoring in the absence of documented OSA; snoring alone is not considered a medical condition, as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

The following minimally invasive surgical procedures are considered not medically necessary for the sole or adjunctive treatment of OSA or upper airway resistance syndrome (UARS) as the evidence is insufficient to determine the effects of the technology on health outcomes:

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COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Note: This policy does not address Uvulopalatopharyngoplasty (UPPP). Laser-assisted uvulopalatoplasty (LAUP) should not be confused with UPPP. For more information regarding UPPP, please see the Related Policies section below.

Obstructive sleep apnea is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. In patients with OSA, the normal pharyngeal narrowing may be accentuated by anatomic factors, such as a short, fat “bull” neck, elongated palate and uvula, and large tonsillar pillars with redundant lateral pharyngeal wall mucosa. In addition, OSA is associated with obesity. OSA may also be associated with a variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. Obstruction anywhere along the upper airway can result in apnea. Therefore, OSA is associated with a heterogeneous group of anatomic variants producing obstruction.

The hallmark symptom of OSA is excessive daytime sleepiness, and the typical clinical sign of OSA is snoring, which can abruptly cease and be followed by gasping associated with a brief arousal from sleep. The snoring resumes when the patient falls back to sleep, and the cycle of snoring/apnea/arousal may be repeated as frequently as every minute throughout the night. Sleep fragmentation associated with the repeated arousal during sleep can lead to impairment of daytime activity. For example, adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles (i.e., cars, trucks, heavy equipment). OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to overwhelming sleepiness.

Minimally invasive surgical approaches being evaluated for OSA in adults include the following:

Laser-assisted Uvulopalatoplasty: LAUP is an outpatient alternative that has been proposed as a treatment of snoring with or without associated OSA. In this procedure, superficial palatal tissues are sequentially reshaped using a carbon dioxide laser. The extent of the surgery is typically different than standard UPPP, since only part of the uvula and associated soft palate tissues are reshaped. The procedure, as initially described, does not remove or alter tonsils or lateral pharyngeal wall tissues. The patient undergoes from 3 to 7 sessions at 3- to 4-week intervals. One purported advantage of LAUP is that the amount of tissue ablated

can be titrated such that the treatment can be discontinued once snoring is eliminated. LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, which raises its own issues of safety and, in particular, effectiveness.

Radiofrequency Ablation (RFA) of Palatal Tissues and the Tongue: RFA of the soft palate is similar in concept to LAUP, although a different energy source is used. Radiofrequency is used to produce thermal lesions within the tissues rather than using a laser to ablate the tissue surface, which may be painful. For this reason, RFA appears to be growing in popularity as an alternative to LAUP. In some situations, radiofrequency of the soft palate and base of tongue are performed together as a multilevel procedure.

Tongue Base Suspension: In this procedure, the base of the tongue is suspended with a suture that is passed through the tongue and then fixated with a screw to the inner side of the mandible, below the tooth roots. The aim of the suspension is to make it less likely for the base of the tongue to prolapse during sleep.

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

Hypoglossal Nerve Stimulation: Stimulation of the hypoglossal nerve results in contraction of the genioglossus muscle, the largest upper airway dilator muscle. This causes tongue protrusion and stiffening of the anterior pharyngeal wall, potentially leading to a decrease in apneic events. Hypoglossal nerve stimulation systems include an implantable neurostimulator, stimulating leads, and electrodes. Intermittent stimulation systems also include respiratory sensing leads.

There is a great range of severity of OSA, with symptoms ranging from snoring only to severe excessive daytime sleepiness or hypertension. Four RCTs, rated as high quality, were identified for laser-assisted palatoplasty and radiofrequency ablation. Study results were mixed and inconclusive for apnea/hypopnea index (AHI), and showed no benefit on daytime sleepiness or quality of life.

A randomized controlled trial (RCT) from 2009 compared efficacy and side effects of 2 tongue-based procedures (RFA or tongue-base suspension) when combined with UPPP in patients with moderate-to-severe sleep apnea (AHI ≥ 15). (15) Patients with a body mass index (BMI) of 35 kg/m² or greater were excluded. Although interpretation of results is limited by the lack of a control group treated with UPPP alone, success rates for the combined procedures (defined as an $\geq 50\%$ reduction and final AHI < 15) were 51% to 57%, respectively. BMI was the main predictor of success, with success rates of only 10% to 12.5% in patients with a BMI between 30 and < 35 kg/mg². Morbidity was higher with the tongue suspension procedure.

The literature on palatal implants consists of 3 RTCs and additional case series with medium-term follow-up. Evidence from sham-controlled trials shows a statistically significant but modest reduction in AHI and improvement in lowest oxygen saturation compared to placebo, with limited effects on daytime sleepiness. Additional study is needed to determine whether there is a defined subset of patients who might benefit from this procedure. Studies with longer term follow-up are also needed to evaluate the potential for extrusion of the implants at longer time intervals.

One system for hypoglossal nerve stimulation has been approved by the U.S. Food and Drug Administration (FDA). At this time, hypoglossal nerve stimulation has been studied only in case series, the largest series had 12-month follow-up. In addition, a pivotal study on the HGNS system was terminated and the company ceased operations when it was determined that the trial was unlikely to meet its primary end point. Additional study with existing devices is needed to permit conclusions regarding the effect of this treatment on health outcomes.

Minimally invasive surgical procedures have limited efficacy in patients with mild-to-moderate OSA and have not been shown to improve Apnea/Hypopnea Index or excessive daytime sleepiness in adult patients with moderate-to-severe OSA. These are considered not medically necessary as there is no proven efficacy.

CODING

The following codes are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:

- 41512** Tongue base suspension permanent suture technique
- 41530** Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
- S2080** Laser-assisted uvulopalatoplasty (LAUP)

For those procedures without a specific CPT code, claims should be filed with an appropriate unlisted procedure code.

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

- Provider Update, February 2019
- Provider Update, February 2018
- Provider Update, January 2017
- Provider Update, July 2015
- Provider Update, September 2013

REFERENCES

1. Ferguson KA, Heighway K, Ruby RR. A randomized trial of laser-assisted uvulopalatoplasty in the treatment of mild obstructive sleep apnea. *Am J Respir Crit Care Med.* Jan 1 2003;167(1):15-19. PMID 12502473
2. Handler E, Hamans E, Goldberg AN, et al. Tongue suspension: an evidence-based review and comparison to hypopharyngeal surgery for OSA. *Laryngoscope.* Jan 2014;124(1):329-336. PMID 23729234
3. Farrar J, Ryan J, Oliver E, et al. Radiofrequency ablation for the treatment of obstructive sleep apnea: a meta-analysis. *Laryngoscope.* Oct 2008;118(10):1878-1883. PMID 18806478
4. Back LJ, Liukko T, Rantanen I, et al. Radiofrequency surgery of the soft palate in the treatment of mild obstructive sleep apnea is not effective as a single-stage procedure: A randomized single-blinded placebo-controlled trial. *Laryngoscope.* Aug 2009;119(8):1621-1627. PMID 19504550
5. Mair EA, Day RH. Cautery-assisted palatal stiffening operation. *Otolaryngol Head Neck Surg.* Apr 2000;122(4):547-556. PMID 10740176
6. Pang KP, Terris DJ. Modified cautery-assisted palatal stiffening operation: new method for treating snoring and mild obstructive sleep apnea. *Otolaryngol Head Neck Surg.* May 2007;136(5):823-826. PMID 17478223
7. Wassmuth Z, Mair E, Loube D, et al. Cautery-assisted palatal stiffening operation for the treatment of obstructive sleep apnea syndrome. *Otolaryngol Head Neck Surg.* Jul 2000;123(1 Pt 1):55-60. PMID 10889482
8. Steward DL, Huntley TC, Woodson BT, et al. Palate implants for obstructive sleep apnea: multi-institution, randomized, placebo-controlled study. *Otolaryngol Head Neck Surg.* Oct 2008;139(4):506-510. PMID 18922335
9. Friedman M, Schalch P, Lin HC, et al. Palatal implants for the treatment of snoring and obstructive sleep apnea/hypopnea syndrome. *Otolaryngol Head Neck Surg.* Feb 2008;138(2):209-216. PMID 18241718

10. Maurer JT, Sommer JU, Hein G, et al. Palatal implants in the treatment of obstructive sleep apnea: a randomised, placebo-controlled single-centre trial. *Eur Arch Otorhinolaryngol.* Jul 2012;269(7):1851-1856. PMID 22228439
11. Walker RP, Levine HL, Hopp ML, et al. Palatal implants: a new approach for the treatment of obstructive sleep apnea. *Otolaryngol Head Neck Surg.* Oct 2006;135(4):549-554. PMID 17011415
12. Walker RP, Levine HL, Hopp ML, et al. Extended follow-up of palatal implants for OSA treatment. *Otolaryngol Head Neck Surg.* Nov 2007;137(5):822-827. PMID 17967653
13. Neruntarat C. Long-term results of palatal implants for obstructive sleep apnea. *Eur Arch Otorhinolaryngol.* Jul 2011;268(7):1077-1080. PMID 21298386
14. Strollo PJ, Jr., Soose RJ, Maurer JT, et al. Upper-airway stimulation for obstructive sleep apnea. *N Engl J Med.* Jan 9 2014;370(2):139-149. PMID 24401051
15. Strollo PJ, Jr., Gillespie MB, Soose RJ, et al. Upper airway stimulation for obstructive sleep apnea: durability of the treatment effect at 18 months. *Sleep.* 2015;38(10):1593-1598. PMID 26158895
16. Woodson BT, Soose RJ, Gillespie MB, et al. Three-year outcomes of cranial nerve stimulation for obstructive sleep apnea: the STAR Trial. *Otolaryngol Head Neck Surg.* Jan 2016;154(1):181-188. PMID 26577774
17. Soose RJ, Woodson BT, Gillespie MB, et al. Upper airway stimulation for obstructive sleep apnea: self-reported outcomes at 24 months. *J Clin Sleep Med.* Jan 2016;12(1):43-48. PMID 26235158
18. Woodson BT, Gillespie MB, Soose RJ, et al. Randomized controlled withdrawal study of upper airway stimulation on OSA: short- and long-term effect. *Otolaryngol Head Neck Surg.* Nov 2014;151(5):880-887. PMID 25205641
19. Kezirian EJ, Goding GS, Jr., Malhotra A, et al. Hypoglossal nerve stimulation improves obstructive sleep apnea: 12-month outcomes. *J Sleep Res.* Feb 2014;23(1):77-83. PMID 24033656
20. Certal VF, Zaghi S, Riaz M, et al. Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: A systematic review and meta-analysis. *Laryngoscope.* May 2015;125(5):1254-1264. PMID 25389029
21. Aurora RN, Casey KR, Kristo D, et al. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. *Sleep.* Oct 1 2010;33(10):1408-1413. PMID 21061864
22. Caples SM, Rowley JA, Prinsell JR, et al. Surgical modifications of the upper airway for obstructive sleep apnea in adults: a systematic review and meta-analysis. *Sleep.* Oct 1 2010;33(10):1396-1407. PMID 21061863
23. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics.* Sep 2012;130(3):e714-755. PMID 22926176
24. 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 August 28, 2017.
25. American Academy of Otolaryngology -- Head and Neck Surgery. Position Statement: Surgical Management of Obstructive Sleep Apnea. 2014; <http://www.entnet.org/Practice/policySurgicalMgmtApnea.cfm>. Accessed September 1, 2017.

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