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

EFFECTIVE DATE: 02|01|2020
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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

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

- Age ≥ 22 years; **AND**
- AHI ≥ 15 with less than 25% central apneas; **AND**
- CPAP failure (residual AHI ≥ 15 or failure to use CPAP ≥ 4 hr per night for ≥ 5 nights per week) or inability to tolerate CPAP; **AND**
- Body mass index ≤ 32 kg/m2; **AND**
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy.

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 >10 and <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 for age; **AND**
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy.

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products via the online tool for participating providers.

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 covered for all indications other than listed above.

All interventions, including LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, are considered not covered 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:

- 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 other than listed above.

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.

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 Uvulopalatopharygnoplasty (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 causes tongue protrusion and stiffening of the anterior pharyngeal wall, potentially decreasing apneic events. For patients with moderate-to-severe sleep apnea who have failed or are intolerant of CPAP, the alternative would be an established surgical procedure.

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 $\geq$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.

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

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

BlueCHiP for Medicare and Commercial Products

The following CPT code is medically necessary for surgical treatment of snoring and obstructive sleep apnea syndrome when the medical criteria above is met. Please see the Prior Authorization via Web-Based Tool for Procedures policy for other indications:

64568 Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

The following codes are considered medically necessary when filed with the one of the diagnosis below:

0466T Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)

0467T Revision or replacement of chest wall respiratory sensor electrode or electrode array, including connection to existing pulse generator

ICD-10 Codes: G47.30-G47.39

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)
C9727 Insertion of implants into the soft palate; minimum of three implants

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

RELATED POLICIES

Prior Authorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, February 2020
Provider Update, February 2019
Provider Update, February 2018
Provider Update, January 2017
Provider Update, July 2015

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