OVERVIEW
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. This policy addresses minimally invasive surgical approaches being evaluated for OSA in adults.

PRIOR AUTHORIZATION
Prior Authorization is not required.

POLICY STATEMENT
BlueCHiP for Medicare:
Tongue base suspension procedures are medically necessary for BlueCHiP for Medicare members, all other minimally invasive surgeries for the treatment of snoring and obstructive sleep apnea are considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

Commercial
Minimally invasive surgeries and tongue base suspension procedures, for the treatment of snoring and obstructive sleep apnea are considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA
None.

BACKGROUND
Note: This policy does not address Uvulopalatopharyngoplasty (UPPP) which is a covered service. Laser-assisted uvulopalatoplasty (LAUP) should not be confused with UPPP.

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. 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.

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

**Laser-assisted Uvulopalatoplasty (LAUP):** 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.

There is a great range of severity of OSA, with symptoms ranging from snoring only to severe excessive daytime sleepiness or hypertension. If OSA is considered mild (AHI between 5 and 15) and snoring is the only manifestation, intervention is considered not medically necessary.

Four RCTs, rated as high quality, were identified for laser-assisted palatoplasty (LAUP) and radiofrequency ablation (RFA). Study results were mixed and inconclusive for apnea/hypopnea index (AHI), and showed no benefit on daytime sleepiness or quality of life.

An 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 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 ≥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/m2. Morbidity was higher with the tongue suspension procedure.

The literature on palatal implants consists of 3 randomized controlled trials 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.

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

**COVERAGE**

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable "Services Not Medically Necessary" benefit.

**CODING**

The following code is considered medically necessary for BlueCHiP for Medicare members only. For all other products it is considered not medically necessary.

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**RELATED POLICIES**

None.

**PUBLISHED**

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**REFERENCES**


