Cohere Medicare Advantage Policy - Obstructive Sleep Apnea Surgeries (Non-Covered Procedures)

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Guideline Information:

Specialty Area: Sleep Medicine
Guideline Name: Cohere Medicare Advantage Policy - Obstructive Sleep Apnea Surgeries (Non-Covered Procedures)

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Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Obstructive Sleep Apnea Surgeries (Non-Covered Procedures)

Benefit Category

Not Applicable

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-2]

- Local Coverage Determination (LCD): Surgical treatment of obstructive sleep apnea (OSA) (L34526)
- Billing and Coding: Surgical treatment of obstructive sleep apnea (OSA) (A56905)

Recommended Clinical Approach

This service is clinically unproven and not medically necessary.

Obstructive sleep apnea (OSA) is a condition where multiple episodes of partial or complete closure of the upper airway during sleep may occur. These often frequent episodes may lead to pauses in breathing (apnea or hypopnea) that can last for greater than 10 seconds, and may be followed by awakening or rapid breathing. Both adults and children may be affected by OSA. Diagnostic testing is necessary to determine the presence of OSA. While non-surgical treatments exist (e.g., positive airway pressure [PAP], oral appliance therapy), surgery may be proposed to reduce the high risk of hypertension, atrial fibrillation, heart failure, and other serious associated conditions due to lack of oxygen in the bloodstream. While there are several established and clinically proven OSA surgeries available, other OSA surgical technologies are emerging and under investigation.[3-4]

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of obstructive sleep apnea surgeries. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Potential risks of OSA surgeries include short-term postoperative complications such as swallowing difficulties, velopharyngeal insufficiency, infection, or taste disturbances. Long-term adverse effects may include failure to provide a cure for the OSA as well as intolerance to PAP therapy (Smith et al. 2015).[5]
- Consideration of potential delays or denials in treatment leading to worsened patient outcomes. Inability to perform OSA surgery due to delays or denials in treatment can result in cardiovascular compromise for the patient as well as decreased quality of life due to inadequate sleep. Individuals with increased body mass index (BMI) may be at greater risk for OSA and its complications, according to a 2021 guideline for the American Academy of Sleep Medicine by Kent et al.[6]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The potential clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to obstructive sleep apnea (OSA) surgeries. OSA surgical approaches may improve sleep quality for individuals who have not been successfully treated with non-surgical interventions such as positive airway pressure (PAP) therapy due to airway obstruction in the palatal and lingual regions.
- Reduction in complications and adverse effects from unnecessary procedures. It is crucial to avoid unnecessary surgery, as in the future, additional invasive management may be required.
- Appropriate management of obstructive sleep apnea which has not been successfully treated by non-surgical interventions. Individuals may not have been able to tolerate PAP therapy due to claustrophobia

or other intolerance, or their OSA symptoms may have persisted despite the use of PAP therapy.
- Enhanced overall patient satisfaction and healthcare experience. Individuals may experience better overall health following OSA surgery as their sleep improves and there is a reduction in cardiovascular complications and improved quality of life.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

➔ The following **obstructive sleep apnea surgeries** are not considered appropriate, as they are clinically unproven and not medically necessary. There is inconclusive evidence of the effectiveness of **ANY** of the following procedures:
- ◆ Submucosal radiofrequency ablation of the tongue base[1, 7-8]; **OR**
- ◆ Somnoplasty palate reduction[1]; **OR**
- ◆ Uvulectomy as a stand-alone procedure for the treatment of OSA; **OR**
- ◆ Insertion of implants into the soft palate (Pillar Procedure)[1, 8-9]; **OR**
- ◆ Laser-assisted uvulopalatoplasty (LAUP)[1, 8, 10-11].

Non-Indications

➔ **Obstructive sleep apnea (OSA) surgeries** are not considered appropriate if **ANY** of the following is **TRUE**:
- ◆ This is not applicable, as there are no indications.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session
42140	Uvulectomy, excision of uvula
42299	Unlisted procedure, palate, uvula
C9727	Insertion of implants into the soft palate; minimum of three implants
S2080	Laser-assisted uvulopalatoplasty (LAUP)

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Aurora et al. (2010) developed practice parameters for surgical modifications of the upper airway for obstructive sleep apnea in adults for the American Academy of Sleep Medicine (AASM). In this systematic review, the group recommended diagnosis of sleep apnea before initiating surgery, and included discussion of procedures such as tracheostomy, maxillo-mandibular advancement (MMA), laser-assisted uvulopalatoplasty (LAUP), uvulopalato-pharyngoplasty (UPPP), radiofrequency ablation (RFA), and palatal implants. UPPP as a sole procedure does not reliably normalize the apnea-hypopnea index (AHI) in moderate to severe OSA syndrome. LAUP was not recommended due to low-quality published evidence. LAUP usually does not normalize the AHI and no support was found in the literature for improvement in secondary outcomes. Additionally, the possibility of OSA symptom worsening exists. Very low quality evidence (case series and only one randomized controlled trial) exists to support the use of radiofrequency ablation, and long-term sequelae of RFA use were not published. The group concluded that there is a lack of rigorous data evaluating outcome measures and which populations would benefit from these surgical treatments. Palatal implants were described as an emerging treatment based on very low quality evidence. The group stated that it is difficult to predict if it will ultimately be found to be a reliably effective treatment option.[8]

Khasawneh et al. (2021) conducted a small study of 30 patients who underwent pillar implants for treatment of snoring and excessive daytime sleepiness. Limitations of the study included, in addition to the small study size, a lack of placebo controls due to the inappropriate nature of sham studies. Follow-up sleep studies were not conducted on all study participants due to cost constraints. Additionally, many of the study participants did not undergo polysomnography, and several participants experienced snoring as their only symptom. Longer term, larger studies were stated to be needed to predict long-term efficacy.[9]

Camacho and colleagues (2017) published a systematic review and meta-analysis regarding laser-assisted uvulopalatoplasty (LAUP) for obstructive sleep apnea (OSA) treatment involving 717 patients in 23 studies

of adult patients. This meta-analysis was based on case series analysis only without controls. The group found a 32% reduction in apnea-hypopnea index (AHI) although the lowest oxygen saturation (LSAT) only minimally changed. The individual data found a success rate of 23%, a cure rate of 8%, and 44% of patients experienced a worsening of AHI. LAUP was recommended by the group to be performed with caution or not at all based on the unfavorable results of the currently published studies.[10]

Littner et al. (2001) reviewed the evidence for laser-assisted uvulopalatoplasty (LAUP) as the basis for the development of a practice parameter for the American Academy of Sleep Medicine (AASM). The group stated that adequate controlled studies for LAUP were not found in peer-reviewed journals. This agreed with AASM's 1994 practice parameters for LAUP, and the group maintained their non-recommendation for LAUP as a treatment for sleep-related breathing disorders. The parameter does state that LAUP may be comparable to uvulopalatopharyngoplasty (UPPP) for the treatment of snoring.[11]

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) published a 2012 updated position statement for submucosal ablation of the tongue base for OSAS. This guideline cited a number of non-randomized studies with low numbers of participants. The group commented that the majority of patients studied were not morbidly obese and experienced mild to moderate OSA. The studies cited that compared ablation with CPAP found similar effectiveness of both therapies.[12]

No current, peer-reviewed studies were found to support the use of uvulectomy as a stand-alone procedure for the treatment of obstructive sleep apnea.

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Clinical Guideline Revision History/Information

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