Cohere Medicare Advantage Policy - Oral Appliance Therapy for Obstructive Sleep Apnea (OSA)

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

Specialty Area: Sleep Medicine
Guideline Name: Cohere Medicare Advantage Policy - Oral Appliance Therapy for Obstructive Sleep Apnea (OSA)

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

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Medical Necessity Criteria

Service: Oral Appliance Therapy for Obstructive Sleep Apnea (OSA)

Benefit Category

Not Applicable

Related CMS Documents

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

- Local Coverage Determination (LCD). Oral appliances for obstructive sleep apnea (L33611)

Recommended Clinical Approach

Oral appliance therapy is a non-invasive treatment for patients who have been diagnosed with obstructive sleep apnea (OSA). These patients may not have been successful with positive airway pressure (PAP) therapy due to intolerance or noncompliance. Customized for the patient, oral appliances for OSA treatment include mandibular advancement or tongue retraining devices.[2] Oral appliances for OSA treatment should be fitted, adjusted, and monitored by an otolaryngologist or a qualified dentist with sleep medicine training.[3-5] The United States Food and Drug Administration (FDA) granted approval for the following devices for the treatment of obstructive sleep apnea (OSA): True Function Adjustable Herbst Appliance (2017), Narval CC (2011), and TAP II (2006).[6-8]

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 oral appliance therapy for obstructive sleep apnea (OSA). 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:

- A 2019 report by the US Veterans Administration/Department of Defense identified risks of oral appliance therapy use for the treatment of mild to moderate OSA. Patients with unstable dentition, morbid obesity, and serious cardiovascular or pulmonary disorders may be better suited for PAP therapy. Side effects include pain in the teeth or jaws, change in bite, or movement of the teeth.[9]
- Several medical society guidelines, including those from the American Academy of Sleep Medicine (AASM) and the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), recommend that PAP therapy be tried and failed before oral appliance therapy can be initiated. This recommendation or requirement can delay treatment for patients who may have been successfully treated with oral appliance therapy.[10-11]
- Johal et al. (2023) state that while PAP therapy is the "gold standard" treatment for OSA, oral appliance therapy is a recognized alternative treatment. Patients who are nonadherent with or of PAP therapy may be more successful with oral appliance therapy and therefore reduce the potentially dangerous physical and mental effects of OSA.[12]
- Increased healthcare costs and complications from the inappropriate use of OSA-related services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to the procedure. In 2022, the American Academy of Dental Sleep Medicine (AADSM) released a standards for practice document supporting the use of oral appliance therapy in sleep-related breathing disorders. While not recommended as a first-line treatment for any level of severity of OSA, they state that it may be useful when other therapies have been attempted and have failed. They confirm that studies have shown oral appliance therapy is comparable to PAP therapy in reducing symptoms such as daytime sleepiness and hypertension, and is strongly preferred by many patients.[13]
- Potential to mitigate the risk of morbidity from OSA which may otherwise have gone untreated.

- Reduction in complications and adverse effects from unnecessary procedures. Skalna et al. (2019) studied oral appliance effectiveness and patient satisfaction with a patient enrollment of 58 adults (40 men and 18 women with a mean age of 50.5 years). The majority were overweight with a mean baseline AHI of 31.3. These patients were stated to have been intolerant to PAP therapy. 86% of patients experienced a reduction in AHI value, within a range of 5 to 25 AHI units. Positive responses regarding device effectiveness were recorded in 76.5% of patients. The majority of these patients wore the appliance nightly. Patient satisfaction was found to have similar percentages.[14]

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 and ensure 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

➔ **Oral appliance therapy for obstructive sleep apnea (OSA)** with a custom-fabricated mandibular advancement oral appliance (E0486) is considered appropriate if **ANY** of the following is **TRUE**[1, 15]:

- ◆ **ALL** of the following:
  - The patient has an in-person clinical evaluation by the treating practitioner prior to the sleep test to assess the patient for OSA testing; **AND**
  - The patient has a Medicare-covered sleep test that results in **ANY** of the following[1, 10-11]:
    - The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; **OR**

        - The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of **ANY** of the following:
            - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **OR**
            - Hypertension, ischemic heart disease, or history of stroke; **OR**
        - The AHI or RDI is greater than 30 and **ANY** of the following:
            - The patient is not able to tolerate a positive airway pressure (PAP) device; **OR**
            - The treating practitioner determines that the use of a PAP device is contraindicated; **AND**
    - The oral appliance is ordered by the treating practitioner following a review of the report of the sleep test*; **AND**
    - The ordering appliance is provided and billed for by a licensed dentist (DDS or DMD)[1, 9, 13]; **OR**
- Replacement of an oral appliance for OSA for **ANY** of the following:
    - Change in structure of the patient's oral cavity or teeth; **OR**
    - The appliance is worn due to excessive use and unable to be repaired; **OR**
    - The appliance has reached a 5-year reasonable useful lifetime (RUL).

***NOTE**: The treating practitioner should be different from the practitioner who initially evaluated the patient for OSA.

Non-Indications

- → **Oral appliance therapy for obstructive sleep apnea** is not considered appropriate if **ANY** of the following is **TRUE**[1]:
    - The criteria listed in the Indications section above have not been met; **OR**
    - A prefabricated oral appliance (E0485) has been ordered for the patient[1, 15]; **OR**
    - Replacement of an oral appliance in cases of misuse or abuse.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

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

Medical Evidence

Johal et al. (2023) state that while PAP therapy is the "gold standard" treatment for OSA, oral appliance therapy is a recognized alternative treatment. Patients who are nonadherent with or intolerant of PAP therapy may be more successful with oral appliance therapy and therefore reduce the effects of OSA. In this systematic review, the writing group examined the treatment outcomes of patients with custom-made, titratable intra-oral appliances. These were found to influence patient preferences and adherence. It was noted that prefabricated appliances are not favorable as they cannot adapt to various oral anatomies. Early discontinuation (less than 2 years of usage) of the device by patients was generally related to pain or discomfort, and occurred more often with prefabricated devices.[12]

Trzepizur et al. (2021) conducted a meta-analysis of several RCTs that included 249 adult patients with severe OSA to study the effects of CPAP and titratable mandibular advancement devices (MADs). Study participants had been diagnosed with severe OSA based on an AHI of greater than 30 per hour. MADs used in the trial were required to be custom-made with progressive titration. The authors found that titratable MADs produced similar results to PAP related to patient sleepiness and quality of life; however, PAP therapy was more effective in reducing apnea/hypopnea index (AHI). Overall, the study concluded that there were no statistically significant differences related to sleepiness and sleep architecture when MAD and CPAP were compared. Patient preference was higher with MAD resulting in increased adherence to treatment.[16]

Ou et al. (2024) reported on CRESCENT (Cardiosleep Research Program on Obstructive Sleep Apnea, Blood Pressure Control and Maladaptive Myocardial Remodeling—Non-inferiority Trial). The randomized control trial (RCT) on the efficacy of mandibular advancement device (MAD) versus continuous positive airway pressure (CPAP) to reduce ambulatory blood pressure. A total of 220 participants aged 40 years or older were identified; two-thirds had severe obstructive sleep apnea (OSA) and were at-risk for developing cardiovascular disease. Participants were randomly assigned to either the MAD or CPAP group. A greater reduction in secondary ambulatory blood

pressure parameters was identified in the MAD group however, both groups demonstrated improvement in daytime sleepiness.[17]

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Clinical Guideline Revision History/Information

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