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

Clinical Guidelines for Medical Necessity Review

Version: 2
Revision Date: March 6, 2025

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Guideline Information:

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

Date of last literature review: 03/05/2025
Document last updated: 03/05/2025
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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

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.[1] It is recommended that oral appliances for OSA treatment be fitted, adjusted, and monitored by an otolaryngologist or a qualified dentist with sleep medicine training.[2-4] Examples of US Food and Drug Administration (FDA) approved devices for the treatment of obstructive sleep apnea (OSA) include, but are not limited to, the following: True Function Adjustable Herbst Appliance (2017), Narval CC (2011), and TAP II (2006).[5-7]

Medical Necessity Criteria

Indications

- ➔ **Oral appliance therapy for obstructive sleep apnea (OSA)** is considered appropriate if **ANY** of the following are **TRUE**:
  - ◆ **Adult patients** 18 years of age or older and **ALL** of the following:
    - The patient has a confirmed diagnosis* of OSA[8-9]; **AND**
    - The patient has undergone a complete intra-oral and dental examination[10]; **AND**
    - The oral appliance is custom-made for the patient[9, 11-13]; **AND**
    - **ANY** of the following:
      - **ALL** of the following:
        - ◆ Apnea-hypopnea index (AHI) greater than 5 and less than 15 (mild to moderate OSA)[9]; **AND**
        - ◆ **ANY** of the following:
          - Documented failure or intolerance of positive airway pressure (PAP) therapy (e.g., oropharyngeal anatomic abnormalities, persistent apnea or

choking during sleep, claustrophobia, noise or pressure intolerance)[9, 12]; **OR**
- The patient has diagnosed hypertension, ischemic heart disease, history of stroke, diabetes or insomnia; **OR**
- The patient expresses preference of oral appliance therapy instead of PAP therapy following a shared decision-making discussion with the treating practitioner; **OR**

○ The AHI is greater than 15 and **ANY** of the following[9]:
- 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; **OR**

◆ **Pediatric patients** younger than 18 years of age with **ALL** of the following:
- Craniofacial anomalies; **AND**
- Signs and symptoms of OSA; **AND**
- The patient or caregiver is able to safely use the oral appliance[14-16]; **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: OSA diagnosis has been confirmed by a physician specializing in sleep disorders by polysomnography in a facility-based laboratory or with a home-based study using a technically adequate device under the supervision of a physician specializing in sleep disorders.[16]

Non-Indications

➔ **Oral appliance therapy for obstructive sleep apnea (OSA)** is not considered appropriate if **ANY** of the following is **TRUE**:

◆ PAP has not been attempted[8-9]; **OR**

- The patient does not have adequate dentition to support the device[18]; **OR**
- The patient has a seizure disorder[11]; **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

Medical Evidence

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.[19]

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.[20]

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 noncompliant or nontolerant with PAP therapy may be more successful with oral appliance therapy and therefore reduce the potentially dangerous physical and mental 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 was found to be less than 2 years and

generally related to pain or discomfort, and more often with prefabricated devices.[21]

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, resulting in enhanced overall patient satisfaction and healthcare experience.[22]

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Clinical Guideline Revision History/Information

Original Date: February 13, 2025		
Review History		

Version 2	3/6/2025	• Wording changed in Recommended Clinical Approach section to clarify that FDA approved devices listed are examples and not all-inclusive
		• Clarified criteria on p. 4-5 regarding AHIs for mild-moderate OSA
		• Added:
		  ○ The patient has diagnosed hypertension, ischemic heart disease, history of stroke, diabetes or insomnia; **OR**
		  ○ The patient expresses preference of oral appliance therapy instead of PAP therapy following a shared decision-making discussion with the treating practitioner; **OR**
		• Changed RDI greater than 30 to greater than 15 p.5
		• Pediatric patient indications p.5 revised to add patient or caregiver able to safely use the device
		• Removed TMJ from non-indications