See Policy HCPCS CODE section below for any prior authorization requirements

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) for coverage determinations.

For other lines of business, refer to the Policy Criteria section below:

POLICY CRITERIA

Fabricated Oral Appliance

I. The use of a fabricated oral appliance, also referred to as a mandibular advancement device, for the treatment of obstructive sleep apnea (OSA) may be considered medically necessary and covered when at least one of the following (A.-C.) criteria are met:

A. The patient has been diagnosed, using polysomnography or home sleep apnea testing, with mild OSA (defined as apnea hypopnea index [AHI] or respiratory disturbance index [RDI] of 5 to 14 events per hour) and is symptomatic with at least one of the following (1.-6.):
   1. Excessive daytime sleepiness characterized by at least one of the following (a.-c.)
      a. Questionnaires (Epworth Sleepiness Scale [ESS], Belin, STOP BANG); or
      b. Sleepiness that interferes with activities of daily living (ADLs) and is not explained by other conditions; or
      c. Inappropriate daytime napping; and/or
2. Impaired cognition; or
3. Mood disorders; or
4. Insomnia; or
5. Documented hypertension; or
6. Ischemic heart disease; or
7. History of stroke; or

**Note:** Positive airway pressure (PAP) therapy would be considered a duplicative service and not covered in mild OSA if member chose oral appliance therapy.

B. The patient has been diagnosed, using polysomnography or home sleep apnea testing, with moderate OSA (defined as AHI or RDI of 15 to 30 events per hour) and meets at least one of the following (1.-2.) criteria:
   1. The patient meets both of the following criteria (a.-b.):
      a. The patient has undergone a 2 month active trial of a positive airway pressure (PAP) device, including mask readjustment and pressure changes, but is still unable to tolerate PAP; and
      b. A consult with a sleep specialist to ensure the PAP trial was adequate and all treatment options were discussed; or
   2. The use of a PAP device is contraindicated.

C. The patient has been diagnosed, using polysomnography or home sleep apnea testing, with severe OSA (defined as AHI or RDI greater than 30 events per hour) and meets at least one of the following (1.-2.) criteria:
   1. The patient meets both of the following criteria (a.-b.):
      a. The patient has undergone a 2 month active trial of a positive airway pressure (PAP) device, including mask readjustment and pressure changes, but is still unable to tolerate PAP; and
      b. A consult with a sleep specialist to ensure the PAP trial was adequate and all treatment options were discussed; or
   2. The use of a PAP device is contraindicated.

**II.** The use of a fabricated oral appliance, also referred to as a mandibular advancement device, for the treatment of obstructive sleep apnea (OSA) is considered not medically necessary and is not covered when criterion I. above is not met.

**Replacement of Fabricated Oral Appliance**

**III.** Replacement of a fabricated oral appliance may be considered medically necessary and covered when it has reached the end of its five year reasonable use lifetime (RUL) or when wear and tear renders the item non-functioning and non-repairable.

**IV.** Replacement of a fabricated oral appliance is considered not medically necessary and is not covered when criterion III. above is not met.
Prefabricated Oral Appliance

V. The use of a prefabricated oral appliance for the treatment of obstructive sleep apnea (OSA) is considered investigational and is not covered.

Link to Policy Summary

HCPCS CODES

<table>
<thead>
<tr>
<th>All Lines of Business</th>
<th>Prior Authorization Required</th>
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<tbody>
<tr>
<td>E0486</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment</td>
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DEFINITIONS

- **Apnea**: the cessation of airflow for at least 10 seconds
- **Hypopnea**: abnormally slow or shallow breathing resulting in reduced airflow
- **Apnea-hypopnea index (AHI)**: the number of apnea and hypopnea events per hour of sleep; used to indicate the severity of sleep apnea
- **Respiratory disturbance index (RDI)**: the number of apnea and hypopnea events per hour of sleep plus the number of respiratory-effort related arousals (RERAs) per hour of sleep
- **Respiratory-effort related arousals (RERAs)**: an abnormal breathing event which does not meet the criteria for an apnea of hypopnea, but is an arousal of sleep associated with a respiratory event noted during a sleep study
- **Mild sleep apnea**: AHI or RDI score of 5 to 14 and is typically associated with involuntary daytime sleepiness during activities that require little attention such as reading or watching television.
- **Moderate sleep apnea**: AHI or RDI score of 15 to 30 associated with involuntary sleepiness during activities that require moderate attention such as meetings or presentations.
- **Severe sleep apnea**: AHI or RDI score of greater than 30 and is typified by daytime sleepiness during activities that require active attention such as driving or talking. The score may exceed 100 in patients with very severe OSA.
• **Epworth Sleepiness Scale (ESS):** a self-administered questionnaire that asks respondents to rate their usual chances of dozing off or falling asleep while engaged in different activities
• **Excessive daytime sleepiness:** a score of > 10 on the ESS

**DESCRIPTION**

**Obstructive Sleep Apnea (OSA)**

OSA is a breathing disorder that results in either a decrease or complete cessation of airflow during sleep.1 “Airflow obstruction arises when the muscles in the back of the throat fail to keep the airway open. These muscles support the soft palate, uvula, tonsils, and tongue. When the muscles relax too much, the airway narrows or closes during inhalation.”2 Patients with OSA experience apneas (breathing cessation) and/or hypopneas (marked reduction in breathing volume) during sleep, which causes blood oxygen levels to fall. This cessation of oxygen results in periods of silence followed snorting, choking, or gasping upon continuation of breathing.

Symptoms of OSA include unrefreshing sleep, excessive daytime sleepiness, loud snoring, morning headaches, nocturnal choking, and/or apneas or choking witnessed by bed partner. According to Hayes, “(p)hysiological effects of untreated OSA include fluctuating blood oxygen levels, increased heart rate, chronic daytime hypertension, and impaired glucose tolerance/insulin resistance.”1 Furthermore, OSA maybe be associated with hypertension, heart disease, stroke, and death.

According to Hayes, “(t)he reference standard for the diagnosis of OSA is the attended in-laboratory sleep test or polysomnograph (PSG), which quantifies the apnea-hypopnea index (AHI).”1 The AHI score is an objective measure of the average number of apneas and hypopneas that occur during an hour of sleep. The AHI score is used to determine OSA severity:

- **Mild OSA:** AHI score of 5 to 14 and is typically associated with involuntary daytime sleepiness during activities that require little attention such as reading or watching television.
- **Moderate OSA:** AHI score of 15 to 30 associated with involuntary sleepiness during activities that require moderate attention such as meetings or presentations.
- **Severe OSA:** AHI score of greater than 30 and is typified by daytime sleepiness during activities that require active attention such as driving or talking. The score may exceed 100 in patients with very severe OSA.

**Mandibular Advancement Device (MAD)**

A MAD appliance is used in the treatment of OSA to reduce or relieve upper airway obstruction by modifying the position of the mandible, tongue, and other oropharyngeal structures. According to Hayes, “MAD appliances cause protrusion, or advancement of the mandible forward relative to the maxilla. Protrusion of the mandible creates space behind the tongue and enlarges the upper airway, thus preventing it from collapse.”1 MADs are either made fabricated (custom-fit) or prefabricated.
Fabricated MADs require dental impressions and bite registration, and additional fine adjustments may be required to optimize mandible advancement and minimize discomfort.

**REVIEW OF EVIDENCE**

**Fabricated Mandibular Advancement Devices**

- In 2015, Bratton et al. conducted a systematic review and meta-analysis to compare the association of continuous positive airway pressure (CPAP) and mandibular advancement devices (MADs) with changes in systolic BP (SBP) and diastolic (DBP) in patients with obstructive sleep apnea.\(^2\)
  
  Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The outcome of interest was absolute change in SBP and DBP from baseline to follow-up.

  Following systematic review, the authors identified 51 studies as eligible for inclusion (n=4888). Of the 51 studies, 3 compared MADs with an inactive control, 1 compared MAD with a CPAP, and 3 compared CPAP, MADs, and inactive control. Compared with an inactive control, MADs were associated with a reduction in SBP of 2.1 mm Hg (95% CI, 0.8 to 3.4 mm Hg; \(P = .002\)) and in DBP of 1.9 mm Hg (95% CI, 0.5 to 3.2 mm Hg; \(P = .008\)). There was no significant difference between CPAP and MADs in their association with change in SBP (−0.5 mm Hg [95% CI, −2.0 to 1.0 mm Hg]; \(P = .55\)) or in DBP (−0.2 mm Hg [95% CI, −1.6 to 1.3 mm Hg]; \(P = .82\)).

  Strengths of this systematic review include the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers and inclusion of a large number of studies. Limitations are present in the poor quality of some selected studies and the heterogeneity present between studies. The authors concluded, “(a)mong patients with obstructive sleep apnea, both CPAP and MADs were associated with reductions in BP. Network meta-analysis did not identify a statistically significant difference between the BP outcomes associated with these therapies.”\(^2\)

- In 2011, the Agency for Healthcare Research and Quality conducted a systematic review of the evidence to evaluate the diagnosis and treatment of obstructive sleep apnea (OSA) in adults.\(^3\) Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. The key questions focused on OSA screening and diagnosis, treatments, associations between apnea-hypopnea index (AHI) and clinical outcomes, and predictors of treatment compliance. For the specific evaluation of mandibular advancement devices (MADs), the authors compared MADs to no treatment, MADs to inactive (sham) oral devices, different types of MADs, and MADs versus continuous positive airway pressure (CPAP).

  Five trials (4 fair/moderate quality, 1 poor quality) compared MAD to no treatment. Individually and after meta-analysis, the studies found significant improvements with MAD in apnea-hypopnea index (AHI), Epworth sleepiness scale (ESS), and other sleep study measures. In comparing MADs to inactive (sham) oral devices, five trials (all fair/moderate quality) were identified. The individual and
meta-analysis results indicated MADs improved most sleep study measures compared to devices without mandibular advancement. Five studies were identified that compared different types of MADs. These studies found little or no differences between different types of methods and use of MAD or other oral devices in sleep study or sleepiness measures. Due to the small size and between-study heterogeneity, there was insufficient evidence to draw conclusions with regards to the relative efficacy of different types of MADs in OSA patients. Ten trials (fair/moderate quality) compared MAD with CPAP. “There was sufficient evidence supporting greater improvements in sleep measures with CPAP as compared to MAD, but only weak evidence indicating no or only small differences favoring CPAP for improving compliance, treatment response, quality of life, or neurocognitive measures.”

This AHRQ systematic review was of very good quality and had several strengths, including:

1. the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers
2. contacting authors of selected studies for additional information or data
3. assessment of heterogeneity and publication bias
4. meta-analyses only being conducted when studies were determined to be homogeneous with respect to population, treatment, and outcome measures
5. sensitivity analyses to evaluate the influence of studies with a high risk of bias or high losses to follow-up

Limitations of this systematic review are seen in the inclusion of studies with a high risk of bias and the potential for publication bias due to a small number of studies included in some meta-analyses. Regarding the use of MADs for OSA, the authors concluded moderate strength of evidence for their efficacy in sleep outcomes. The authors also stated, “(b)ased on direct and indirect comparisons, CPAP appeared to be more effective than MAD. However, given the issues with noncompliance with CPAP, the decision as to whether to use CPAP or MAD will likely depend on patient preference.”

Prefabricated Mandibular Advancement Devices

Systematic Reviews

No systematic reviews were identified which evaluated the use of prefabricated mandibular advancement devices for the treatment of obstructive sleep apnea.

Randomized Controlled Trials (RCT)

In 2008, Vanderveken et al. conducted a randomized cross-over trial to evaluate custom-made (fabricated) and thermoplastic (prefabricated) oral appliances for the treatment of sleep disordered breathing (SDB). They enrolled 38 patients and randomly allocated (blindly) to two different treatment sequences. Treatment sequence A included a custom-made MAD for 4 months, followed by a 1-month washout period, and then a thermoplastic MAD for 4 months. The remaining
patients were randomized to the reversed treatment sequence—a 4 month trial of a thermoplastic MAD, 1 month washout, followed by a 4 month trial of a custom-made MAD. The treatment outcomes of interest included a reduction in snoring, apnea-hypopnea index (AHI), compliance, and Epworth sleepiness scale (ESS) score.

AHI was only statistically significantly reduced using the custom-made MAD (p=0.005). Furthermore, the custom-made MAD reduced snoring more significantly than the thermoplastic device. In regards to compliance, one-third of patients had compliance failure with the thermoplastic device because of insufficient overnight retention. "The total failure rate with the thermoplastic device was 69%, whereas the majority (63%) of these were successfully treated with the custom-made device." At study completion, 82% of the patients preferred the custom-made MAD and 9% had no preference (p<0.0001).

Strengths of this study included the randomized, controlled design using a comparator group. However, significant methodological limitations are present in the small sample size and short follow-up period. Ultimately, the authors concluded "(i)n this study, a custom-made device turned out to be more effective than a thermoplastic device in the treatment of SDB. Our results suggest that the thermoplastic device cannot be recommended as a therapeutic option nor can it be used as a screening tool to find good candidates for mandibular advancement therapy."4

**CLINICAL PRACTICE GUIDELINES**

**Fabricated Mandibular Advancement Devices**

**American Academy of Dental Sleep Medicine/American Academy of Sleep Medicine (AADSM/AASM)**

The 2015 AADSM/AASM evidence-based clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy gave the following recommendations:

- When OA therapy is prescribed by a sleep physician for an adult patient with OSA, the Task Force suggests that a qualified dentist use a custom, titratable appliance over non-custom oral devices. (GUIDELINE)
- The Task Force recommends that sleep physicians consider prescription of OAs, rather than no treatment, for adult patients with OSA who are intolerant of CPAP therapy or prefer alternate therapy. (STANDARD)
  - The guideline further states, "(a)lthough OAs have been shown to improve physiologic sleep parameters, continuous positive airway pressure (CPAP), in our meta-analyses, was found to be superior to OAs in reducing the AHI, arousal index, and oxygen desaturation index and improving oxygen saturation, and therefore, should still generally be the first-line option for treating OSA."5
• The Task Force suggests that qualified dentists provide oversight—rather than no follow-up—of OA therapy in adult patients with OSA, to survey for dental-related side effects or occlusal changes and reduce their incidence. (GUIDELINE)
• The Task Force suggests that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances. (GUIDELINE)
• The Task Force suggests that sleep physicians and qualified dentists instruct adult patients treated with OAs for OSA to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician. (GUIDELINE)

Health Evidence Review Commission (HERC)

The 2014 HERC evidence-based coverage guidance for the treatment of sleep apnea in adults stated, “(m)andibular advancement devices (oral appliances) are recommended for coverage for those for whom CPAP fails or is contraindicated (weak recommendation).”

American Society of Anesthesiologists (ASA)

The 2006 (revised 2014) ASA evidence-based clinical practice guideline for the perioperative management of patients with obstructive sleep apnea stated, “(t)he preoperative use of mandibular advancement devices or oral appliances and preoperative weight loss should be considered when feasible.”

American College of Physicians (ACP)

The 2013 ACP evidence-based clinical practice guideline for the management of obstructive sleep apnea in adults gave the following recommendation:

“ACP recommends mandibular advancement devices (MADs) as an alternative therapy to CPAP treatment for patients diagnosed with OSA who prefer MADs or for those with adverse effects associated with CPAP treatment. (Grade: weak recommendation; low-quality evidence) Evidence showed that MADs have been used as an alternative to CPAP for treatment of OSA. Patients had AHI scores between 18 and 40 events per hour. Evidence to suggest which patients would benefit most from MADs was insufficient. However, MADs can be considered in patients with adverse effects or for those who do not tolerate or adhere to CPAP.”

American Academy of Sleep Medicine (AASM)

The 2006 AASM evidence-based clinical practice guideline for the treatment of snoring and OSA with oral appliances gave the following recommendations:
**Sleep Disorder Treatment: Oral Appliances**

**(All Lines of Business Except Medicare)**

- Although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer them to CPAP therapy, or who do not respond to, are not appropriate candidates for, or who fail treatment attempts with CPAP.
- Oral appliances are appropriate for use in patients with primary snoring who do not respond to or are not appropriate candidates for treatment with behavioral measures such as weight loss or sleep-position change.
- Until there is higher quality evidence to suggest efficacy, CPAP is indicated whenever possible for patients with severe OSA before consideration of oral appliances. Upper airway surgery may also supersede the use of oral appliances in patients for whom these operations are predicted to be highly effective in treating sleep apnea.
- Oral appliances should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint (TMJ), dental occlusion, and associated oral structures.
- Follow-up polysomnography (PSG) or an attended cardiorespiratory (Type 3) sleep study is needed to verify efficacy and may be needed when the symptoms of OSA worsen or recur.
- Patients with OSA who are treated with oral appliances should return for follow-up office visits with the dental specialist at regular intervals to:
  - Monitor patient adherence
  - Evaluate device deterioration or maladjustment
  - Evaluate the health of the oral structures and integrity of the occlusion
  - Assess for signs and symptoms of worsening OSA
- Patients with OSA who are treated with oral appliances should also have periodic follow-up office visits with the referring clinician to assess for signs and symptoms of worsening OSA.\(^9\)

**Prefabricated Mandibular Advancement Devices**

No evidence-based clinical practice guidelines were identified which evaluate the use of prefabricated mandibular advancement devices for the treatment of obstructive sleep apnea.

**POLICY SUMMARY**

Although not as effective as continuous positive airway pressure (CPAP), the use of mandibular advancement devices (MADs) does appear to improve sleep outcomes including, but not limited to, the apnea-hypopnea index (AHI) score, Epworth sleepiness scale (ESS) score, blood pressure, and treatment compliance. The American Academy of Sleep Medicine (AASM) recommends the use of MADs in patients with mild to moderate obstructive sleep apnea (OSA) who prefer, do not respond, or are not appropriate candidates for CPAP. The AASM also recommends a trial of CPAP therapy prior to consideration of an oral appliance in patients with severe OSA. The American Society of Anesthesiologists recommends the preoperative use of MADs, when feasible, in patients with OSA. The American College of Physicians, Health Evidence Review Commission, and the American Academy of Dental Sleep Medicine also recommends the use of MADs in patients who fail treatment with CPAP.
There was insufficient evidence to support the efficacy of prefabricated mandibular advancement devices (MADs) for the treatment of obstructive sleep apnea (OSA). Further studies of good methodological quality are required to demonstrate the clinical utility of this OSA treatment option. Furthermore, no evidence-based clinical practice guidelines were identified which recommended prefabricated MADs for the treatment of OSA.

**INSTRUCTIONS FOR USE**

Providence Health Plan (PHP) Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. PHP Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. PHP reserve the right to determine the application of Medical Policies and make revisions to its Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHP Medical Policy will be resolved in favor of the coverage agreement.

**REGULATORY STATUS**

U.S. Food and Drug Administration

“Mandibular advancement devices (MAD) for sleep apnea are regulated through the FDA as Class II antisnoring devices. The Code of Federal Regulations (CFR) defines intraoral devices for snoring and intraoral devices for snoring and OSA as devices that are worn during sleep to reduce the incidence of snoring and to treat OSA. These devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction. This classification includes palatal-lifting devices, tongue-retaining devices (TRD), and MAD (CDRH, 2009).

In 2002, the FDA issued a Special Controls Guidance Document to support the classification of intraoral devices for snoring and/or OSA as Class II devices. Any firm submitting a 510(k) premarket notification for intraoral devices for snoring and/or OSA needs to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness (CDRH, 2002). An extensive list of commercially available MAD has been approved for marketing by the FDA under the 510(k) clearance process to treat snoring and/or OSA (CDRH, 2010).”

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.
MEDICAL POLICY CROSS REFERENCES

- Sleep Disorder Testing (All Lines of Business Except Medicare)
- Sleep Disorder Testing (Medicare Only)
- Sleep Disorder Treatment: Positive Airway Pressure (All Lines of Business Except Medicare)
- Sleep Disorder Treatment: Positive Airway Pressure (Medicare Only)
- Sleep Disorder Treatment: Surgical (All Lines of Business Except Medicare)
- Sleep Disorder Treatment: Surgical (Medicare Only)

REFERENCES