


MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
Effective Date: 10/1/2021	Medical Policy Number: 46
 10/1/2021	Medical Policy Committee Approved Date: 1/18; 1/19; 3/19; 12/19; 6/2020; 04/2021; 06/2021; 9/2021
Medical Officer Date	

See Policy HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

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) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

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.-7.):

MEDICAL POLICY

**Sleep Disorder Treatment: Oral and
Sleep Position Appliances
(All Lines of Business Except
Medicare)**

1. Excessive daytime sleepiness characterized by **at least one** of the following (a.-b.)
 - a. Sleepiness that interferes with activities of daily living (ADLs) and is not explained by other conditions; **or**
 - b. 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.

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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Replacement of Fabricated Oral Appliance

Note: To receive a replacement device, the patient must receive a prescription from the doctor/dentist who initially made (synthesized) the 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.

Dual PAP with Oral Appliance Therapy

- V. Dual PAP with oral appliance therapy is considered **not medically necessary and not covered**, including but not limited to, as a convenience item (e.g. travel).

Other Appliances

- VI. The use of other appliances for the treatment of obstructive sleep apnea (OSA) or any other sleep disorders are considered **investigational and are not covered**, including but not limited to the following:
 - A. Prefabricated oral appliances
 - B. Bite deprogrammer (CPT 21085) (e.g. AM Align, Morning Repositioner)
 - C. Sleep position trainer (i.e. NightBalance)

Link to [Policy Summary](#)

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
21085	Impression and custom preparation; oral surgical splint
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment
Not Covered	
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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K1001	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required.	
E1399	Durable medical equipment, miscellaneous

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 or 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.
- 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. 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. 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.

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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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.

Bite Deprogrammer

Bite deprogrammers (e.g. AM Align, Morning Reposition) purport to aid in realigning the patient’s mandible following the night-time use of a MAD, during which time jaw positioning may have changed.

Sleep Position Trainer (i.e. NightBalance)

NightBalance is a device worn in a band across the patient’s chest during sleep. When the device detects that the patient is sleeping on his or her back (supine), the device delivers vibrations to prompt the patient to shift to their side, without disturbing sleep. By avoiding supine sleeping, device manufacturers purport to reduce breathing disturbances and improve patient quality of sleep in patients with positional OSA.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of oral appliances for the treatment of obstructive sleep apnea. Below is a summary of the available evidence identified through February 2021.

Fabricated Mandibular Advancement Devices

- In 2021, Hayes published an updated review of systematic reviews evaluating the safety and efficacy of mandibular advancement devices (MAD) for the treatment of sleep apnea.² In total, 1 systematic review (assessing 8 RCTs) and 7 additional primary RCTs were included for review. Sample sizes ranged from 10 to 114 patients in the systematic review; to 50 to 150 patients in the primary studies. Follow-up ranged from 1 week to 4 years. Outcomes of interest included apnea-hypopnea index (AHI), Epworth Sleepiness Scale (ESS) scores, quality of life and complications.

Compared to patients receiving no treatment or UPPP, MAD patients experienced superior improvements in AHI, ESS, and quality of life scores. MAD patients also experienced improved outcomes relative to placebo patients and CPAP for AHI, although not for ESS. No significant differences in outcome were found between MAD and tongue stabilizing device patients.

On the basis of moderate-quality evidence, Hayes concluded that MAD improves sleep-disordered breathing and daytime sleepiness in patients with mild-to-moderate OSA. While MAD patients experienced superior outcomes to patients receiving either no treatment or placebo MAD treatment, CPAP patients experienced the largest reductions in sleep-disordered breathing. Although CPAP is considered the standard of treatment, particularly for patients with severe OSA, MAD therapy was recommended for patients with OSA who might opt to go without treatment or cannot tolerate CPAP therapy. Limitations across individual studies included a lack of long-term follow-up, small sample sizes, a lack of power analyses, high attrition and lack of intention-to-treat analyses. Blinding was also inconsistent in studies comparing MAD with placebo MAD and not possible compared to other interventions (e.g. no treatment, CPAP).

Hayes ultimately assigned a “B” rating (some proven benefit) for MAD instead of no treatment for mild-to-moderate OSA in adults who do not respond to CPAP. Hayes assigned a “C” rating (potential but unproven benefit) for MAD instead of no treatment for severe OSA in adults who do not respond to CPAP. A “D2” rating (insufficient evidence) was assigned for MAD instead of CPAP in patients with severe OSA who prefer MAD over CPAP but who have not undergone a trial of CPAP therapy.

- 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.³ Independent reviewers systematically identified eligible studies, assessed quality, and extracted

MEDICAL POLICY**Sleep Disorder Treatment: Oral and
Sleep Position Appliances
(All Lines of Business Except
Medicare)**

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.”³

- 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.⁴ 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.”⁴

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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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.”⁴

Dual PAP with Oral Appliance Therapy

Nonrandomized studies with very small sample sizes (n= 10 to 16) have published findings from combined PAP and oral appliance therapy investigations.^{5,6} For those who do not tolerate or who fail PAP therapy, oral appliances are often a successful alternative. Reports of nasal-CPAP and MAD, and CPAP with MAD do not currently demonstrate sufficient or greater clinical utility than the existing use of one modality or the other. The literature base for each modality separately, clearly establishes clinical utility in defined populations making appropriate patient-selection possible.

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).⁷ Thirty-eight patients were enrolled in the study and randomly allocated (blindly) to two different treatment sequence. 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—4-month trial of a thermoplastic MAD,

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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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.”⁷ 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.”⁷

Bite Deprogrammer

In 2018 (archived 2019), Hayes published a summary of the published literature assessing the efficacy of the Morning Repositioner to restore proper mandibular alignment after use of an overnight sleep apnea appliance.⁸ The authors did not identify any systematic reviews.

No other studies were identified.

Sleep Position Trainer (i.e. NightBalance)

In 2017, de Ruiter and colleagues conducted a prospective, multi-center randomized controlled trial evaluating the efficacy of the sleep position trainer (SPT) for the treatment of positional obstructive sleep apnea. In total, 99 patients were randomized to receive either SPT or oral appliance therapy (OAT), of which 58 completed the study (29 in each group). Outcomes of interest included OSA severity; adherence, quality of life and adverse events. Follow-up was assessed via polysomnography at 3- and 12-month follow-up. Investigators reported that median AHI scores were significantly improved in SPT patients, although not superior to OAT patients. No between-group differences in adherence were identified. While investigators concluded that SPT demonstrated comparable efficacy to OAT, study limitations undermine results’ generalizability. Limitations included the study’s small sample size, lack of long-term follow-up, and significant attrition at 3-month and 12-month evaluations.

CLINICAL PRACTICE GUIDELINES

Fabricated Mandibular Advancement Devices

AIM Specialty Health

In 2020, AIM issued clinical appropriateness guidelines for sleep disorder management, including appropriate use criteria for diagnostic and treatment management of obstructive sleep apnea using oral appliances.⁹ Investigators concluded that treatment with an oral appliance is appropriate for patients with severe OSA (apnea/hypopnea index [AHI] greater than 30) when the patient is not a candidate for PAP, a PAP trial has not been effective or the patient has tried CPAP but has not been compliant despite a trial and participation in a PAP compliance program.

For patients with mild or moderate OSA, AIM concluded that an oral appliance is appropriate when the patient is not a candidate for PAP, a PAP trial has not been effective, the patient has tried CPAP but has not been compliant despite a trial and participation in a PAP compliance program, or the patient prefers to use an oral appliance rather than PAP as the initial therapy.

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:¹⁰

1. We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea). (STANDARD)
2. When oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, we suggest that a qualified dentist use a custom, titratable appliance over non-custom oral devices. (GUIDELINE)
3. We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy. (STANDARD)
4. We suggest that qualified dentists provide oversight— rather than no follow-up—of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence. (GUIDELINE)
5. We suggest 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)
6. We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits— as opposed to no follow-up—with a qualified dentist and a sleep physician. (GUIDELINE)

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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Oregon Health Authority, 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).”¹¹ The HERC reaffirmed the previously approved coverage guidance in 2017.

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.”¹²

American College of Physicians (ACP)

The 2013 ACP evidence-based clinical practice guideline for the management of obstructive sleep apnea in adults stated the following:¹³

Recommendation 1: ACP recommends that all overweight and obese patients diagnosed with OSA should be encouraged to lose weight. (Grade: strong recommendation; low-quality evidence)

Recommendation 2: ACP recommends continuous positive airway pressure treatment as initial therapy for patients diagnosed with OSA. (Grade: strong recommendation; moderate-quality evidence)

Recommendation 3: ACP recommends mandibular advancement devices as an alternative therapy to continuous positive airway pressure treatment for patients diagnosed with OSA who prefer mandibular advancement devices or for those with adverse effects associated with continuous positive airway pressure treatment. (Grade: weak recommendation; low-quality evidence).

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:¹⁴

- 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.

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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- 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.

Prefabricated Mandibular Advancement Devices

AIM Specialty Health

The 2020 AIM clinical appropriateness guidelines for sleep disorder management state that “prefabricated oral appliances are not considered to be appropriate therapy for obstructive sleep apnea in any clinical situation.”⁹

Bite Deprogrammer

No evidence-based clinical practice guidelines were identified which evaluate the use of bite deprogrammers for the treatment of obstructive sleep apnea.

POLICY SUMMARY

Fabricated Oral Appliances and Replacements

There is enough research to show that the use of custom fabricated 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 in carefully selected patients with obstructive sleep apnea. However, MADs do not appear to be as effective as

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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continuous positive airway pressure (CPAP) in improving clinical outcomes. 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, Oregon Health Authority 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. Therefore, the use of MADs may be considered medically necessary for the treatment of obstructive sleep apnea in patients meeting policy criteria. There is sufficient evidence to show that the use of MADs in those who do not meet policy criteria is considered not medically necessary and is not covered.

For those who need a replacement fabricated oral appliance, a new device may be considered medically necessary 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. Otherwise, a replacement fabricated oral appliance is considered not medically necessary and is not covered.

Dual Positive Airway Pressure with Oral Appliance Therapy

There is enough evidence to show that dual positive airway pressure (PAP) with oral appliance therapy does not improve overall health outcomes versus therapy with either PAP or a medically necessary oral appliance for those with sleep disorders, whether used for as dual therapy or for travel (e.g., as a convenience item). No clinical practice guidelines based on research were identified specifically recommending dual PAP with oral appliance therapy. Therefore, dual PAP with oral appliance therapy is considered not medically necessary and is not covered.

Other Appliances Including Prefabricated Oral Appliance, Bite Deprogrammer and Sleep Position Trainer

There is not enough research to show that other oral appliances used to treat obstructive sleep apnea or any other sleep disorder, improve overall health outcomes. These appliances include, but are not limited to prefabricated oral appliances, bite deprogrammers, and sleep position trainers (NightBalance). Some research may show that one or more of these devices may help patients in select populations, though studies of higher methodological quality are required to demonstrate the clinical utility of these treatment options. In addition, no evidence-based clinical practice guidelines were identified recommending prefabricated oral appliances, bite deprogrammers, and sleep position trainers for any indication. Therefore, the use of these devices to treat sleep disorders including but not limited to obstructive sleep apnea are considered investigational and is not covered.

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company 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. The Companies reserve the right to determine the application of Medical Policies and make revisions to 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 Company 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).”¹

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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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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)

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MEDICAL POLICY	Sleep Disorder Treatment: Oral and Sleep Position Appliances (All Lines of Business Except Medicare)
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