MEDICAL POLICY

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Medical Policy Title	**Medical Management Obstructive Sleep Apnea (OSA)**
Policy Number	**1.01.07**
Current Effective Date	**February 16, 2026**
Next Review Date	**October 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Oral appliances therapy (OAT) is **medically appropriate** for the treatment of obstructive sleep apnea (OSA) when the severity level (e.g., mild, moderate, severe) criteria are met:

A. Mild OSA

1. Documented diagnosis of OSA with Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 5 and ≤ 14, confirmed by a sleep study (e.g., PSG or home sleep study); when **BOTH** of the following criteria are met:

a. At least **ONE** of the following indications:

i. Hypertension;

ii. Heart disease;

iii. Stroke;

iv. Excessive daytime sleepiness;

v. Impaired cognition;

vi. Mood disorders; **or**

vii. Insomnia;

AND

b. The individual cannot tolerate or refuses continuous positive airway pressure (CPAP) therapy; **or**

c. The physician determines that the use of positive airway pressure (PAP) therapy is contraindicated.

B. Moderate OSA

1. Documented diagnosis of OSA with a severity level indicated by an AHI or RDI ≥ 15 and < 30 confirmed by a sleep study when **EITHER** of the following criteria are met:

a. The individual cannot tolerate or refuses CPAP therapy; **or**

b. The physician determines that the use of PAP therapy is contraindicated.

C. Severe OSA

1. Documented diagnosis of OSA with a severity level indicated by AHI or RDI ≥ 30, confirmed by a sleep study when **EITHER** of the following criteria are met:

a. The individual cannot tolerate or refuses CPAP therapy; **or**

b. The physician determines that the use of a PAP device is contraindicated.

II. The use of Oral Appliances (OAs) is **not medically necessary** for the following indications, which include but are not limited to:

A. Upper Airway Resistance Syndrome (UARS) with or without snoring and without a diagnosis of OSA;

B. Primary snoring (e.g., Slow Wave Ds8, and SnoreRX);

C. Temporomandibular joint disorders (TMJD), (refer to CMP 11.01.17 Temporomandibular Joint Disorders for other indications);

D. Central sleep apnea;

III. Prefabricated or non-custom OAs are **not medically necessary**.

IV. Daytime neuromuscular electrical stimulation devices (e.g., eXciteOSA) is **investigational** for the treatment of OSA.

V. The use of a sleep positioning trainer with or without vibration is considered **investigational** for the treatment of positional OSA.

VI. Replacement of a medically necessary OA is **eligible for coverage** after five (5) years, unless there is documented evidence of device failure or a clinically significant change in the patient's condition that necessitates earlier replacement (e.g., tooth loss or major dental reconstruction).

VII. Replacement of a medically necessary oral appliance due to misuse or neglect (e.g., lost, or misplaced) is **ineligible for coverage**.

RELATED POLICIES

Corporate Medical Policy

#1.01.06 Positive Airway Pressure Devices: CPAP, BPAP, APAP and Noninvasive Positive Pressure Ventilators (NIPPV)

#7.01.41 Surgical Management of Sleep Disorders

#11.01.03 Experimental or Investigational Services

#11.01.17 Temporomandibular Joint Disorders (TMJD)

POLICY GUIDELINE(S)

I. Attempts at behavioral modifications and lifestyle changes (e.g., good sleep hygiene, weight loss, avoidance of alcohol consumption in evening, smoking cessation, sleep position change, treatment of nasal congestion) for individuals with UARS and sleep apnea should be an integral part of the treatment regimen for sleep-disordered breathing.

II. The decision for the use and fabrication of an OA should be made by a sleep medicine physician (e.g., somnologist or sleep specialist; ear, nose, and throat [ENT] specialist) or by an experienced dentist/orthodontist in collaboration with a sleep specialist.

III. All impressions, try-ins, and adjustments and repairs are inclusive to the lifetime of the appliance after approval of the device.

DESCRIPTION

Sleep related breathing disorders are characterized by abnormal respiration during sleep, which may or may not also occur during wakefulness. These abnormalities can include pauses in breathing, shallow breathing, or reduced airflow, often leading to fragmented sleep and reduced oxygen levels. Other symptoms can include loud snoring, gasping, choking during sleep, morning headaches, dry mouth, daytime fatigue, sleepiness, mood changes, and cognitive issues. There are several types of sleep related breathing disorders. OSA (the most common type) causes physical blockage of the upper airway typically due to relaxed throat muscles during sleep. OSA in an adult is defined as recurrent episodes of complete or partial obstruction of the upper airway leading to reduced or absent breathing during sleep for greater than 10 seconds.

Upper airway resistance syndrome (UARS) is a milder form of obstructive sleep related breathing. The airway narrows but does not fully close. This can cause sleep fragmentation and fatigue.

Central sleep apnea occurs when the brainstem, which regulates breathing, does not respond appropriately to changes in carbon dioxide levels in the blood. This results in reduced or absent respiratory effort, leading to pauses in breathing during sleep. Central apneas are often linked to heart failure or neurological conditions. The central apneas occur without any airway obstruction.

Sleep related hypoventilation disorders causes inadequate breathing during sleep which can lead to high carbon dioxide levels. Hypoventilation disorders are common in obesity, neuromuscular disorders, or medication use.

Sleep related hypoxemia is sustained low oxygen levels during sleep without elevated carbon dioxide. Often due to lung diseases or other medical conditions.

Oral Appliances (OAs)

OAs can be prefabricated, ready-made, or custom fitted device worn in the mouth during sleep to treat OSA and snoring. They work by repositioning the jaw, tongue, or soft tissues to keep the airway open, allowing for uninterrupted breathing throughout the night. The most common type of oral appliance is the mandibular advancement device (MAD), which is custom made for each individual and adjustable to allow a dentist to modify the degree of jaw advancement as needed. The goal is to achieve the most comfortable and effective position for the individual. Examples of custom oral

appliances include tongue-retaining devices, non-adjustable mandibular repositioning devices (MRDs), and adjustable MRDs. These appliances may be used as an alternative to other medical (e.g., CPAP and surgical (e.g., Uvulopalatopharyngoplasty) interventions.

AIO BREATHE (AIOMEGA LLC, Texas) is a lightweight MAD that increases airway size and repositions the jaw to keep the airway more open during sleep. It is recommended for mild to moderate sleep apnea and snoring.

ProSomnus EVO PH (ProSomnus Sleep Technologies), sleep and snore devices use medical grade polymers and hinge components to reposition and stabilize the jaw during sleep. The OA causes an increase in the pharyngeal space, reducing the risk of upper airway collapse. The device is recommended for snoring and to treat mild to moderate OSA.

iNAP (Somnics Health, Inc.) uses gentle suction to move the tongue forward. No mask or headgear is required.

Vivos (Vivos Therapeutics, Inc) OAs are noninvasive, custom-made devices designed to treat OSA and snoring. They function by repositioning the hard and soft tissues of the airway to enhance airflow and improve upper airway function. The Vivos System gradually remodels the upper airway and jaw structure over time to address the underlying anatomical causes of OSA. Recently, the United States Food and Drug Administration (FDA) approved Vivos OAs the treatment of severe OSA.

Neurostimulators

eXciteOSA is an FDA approved daytime therapy designed to treat snoring and mild OSA by strengthening tongue muscles through neuromuscular electrical stimulation (NMES). It is intended for adults aged 18 and older with an AHI less than 15. The device consists of a mouthpiece with four electrodes, two above and two below the tongue that are connected to a control unit via USB. It delivers electrical pulses to stimulate both intrinsic and extrinsic tongue muscles. This stimulation strengthens the muscles, helping to prevent the tongue from collapsing backward during sleep. As a result, it supports airway patency and contributes to the reduction of snoring and apnea events.

SUPPORTIVE LITERATURE

Oral Appliances (OAs)

The consistent findings among studies support the use of OAs as an alternative treatment method for individuals with sleep-related breathing disorders. A systematic review by Lim et al (2008) concluded that there is evidence indicating oral appliance therapy improves both subjective sleepiness and sleep-disordered breathing when compared to control treatments. Lim et al (2008) also conclude that CPAP appears to be more effective in improving sleep-disordered breathing than OA. The difference in symptomatic response between these two treatments is not significant, although it is not possible to exclude an effect in favor of either therapy.

Rossi et al (2021) conducted a systematic review of 17 randomized controlled trials (RCTs) to assess the clinical effectiveness of OAs in treating OSA. The review included RCTs with at least 50 participants, comparing OAs to CPAP, placebo, surgery, or other interventions. Findings showed that OAs significantly reduced both the AHI and the Oxygen Desaturation Index (ODI), including in some

individuals with severe OSA. Custom-fitted, titratable devices were found to be more effective than non-custom or non-titratable alternatives. While CPAP generally achieved greater reductions in AHI, OAs were associated with higher patient compliance and better tolerability. In cases of mild to moderate OSA, some studies showed that OAs were non-inferior to CPAP. Additionally, improvements in daytime sleepiness (Epworth Sleepiness Scale), snoring, and quality of life were observed, although these outcomes varied across studies.

Beri et al (2023) evaluated the effectiveness of OA therapy in treating OSA, focusing on the use of mandibular advancement devices (MADs) and tongue retaining devices (TRDs). The study used the AHI as the primary outcome measure. The inclusion criteria focused on adults with an AHI greater than 5, treated with MAD or TRD, and compared it to CPAP therapy. The analysis was based on a systematic review and meta-analysis of six randomized controlled trials conducted between 1998 and 2021. OA significantly improve AHI compared to baseline (Mean Difference = 13.40; 95% CI). CPAP outperformed OA in reducing AHI (Mean Difference = 8.40; 95% CI). TRDs showed comparable results to MADs in some studies. Researchers concluded that MADs are effective alternatives for patients with mild to moderate OSA, especially those that are intolerant to CPAP.

Electrical Stimulation Appliances

The current body of evidence supporting non-surgical neuromuscular electrical stimulation for OSA remains limited. High-quality data demonstrating its safety and clinical efficacy are lacking. Well-designed, controlled studies are needed to evaluate its therapeutic effectiveness, safety profile, and long-term outcomes. Two cohort studies (Kotecha et al (2021) and Baptista et al (2021)) studied habitual snorers who were treated with eXciteOSA. Both studies reported a reduction in snoring time measured by the Watch-PAT device and bed-partner-reported snorting was also decreased. A reduction in AHI was noted in those participants with mild OSA in the Kotecha study but there was no clinically significant reduction in AHI reported in the Baptista study. Both the Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI) test showed improvements as reported by the participants as well as the bed partners. These studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is uncertain.

PROFESSIONAL GUIDELINE(S)

The 2015 clinical practice guidelines jointly issued by the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM) recommend oral appliance therapy for adult patients with OSA who are intolerant of CPAP therapy or prefer an alternative treatment. A standard recommendation is a strong recommendation based on high-quality evidence and a guideline is a moderate recommendation based on moderate quality evidence or expert consensus. Clinicians are encouraged to follow the recommendation and that exceptions maybe applied based on the individual circumstances.

Primary Snoring (No OSA)
Sleep physicians should prescribe oral appliances instead of offering no treatment for adults seeking help for primary snoring without obstructive sleep apnea. (Standard)

- OSA – Custom Devices Preferred
  When treating adults with OSA sleep physicians should recommend that a qualified dentist provide a custom, adjustable OAs rather than a non-custom device. (Guideline)
- OSA – CPAP Intolerance or Preference
  For adults with obstructive sleep apnea who cannot tolerate CPAP or prefer another option, sleep physicians should consider prescribing OA instead of leaving the condition untreated. (Standard)
- Dental Oversight
  Qualified dentists should monitor patients using OAs for OSA to detect and minimize dental side effects or bite changes, rather than providing no follow-up. (Guideline)
- Follow-Up Sleep Testing
  Sleep physicians should conduct follow-up sleep studies to confirm or improve the effectiveness of OA therapy, rather than relying on follow-up without testing. (Guideline)

The American Academy of Dental Sleep Medicine (AADSM) released an updated position statement in October 2022, on the use of OAT for the treatment of OSA. The statement affirms that OAT is an effective treatment for both OSA and snoring, and should be considered a first-line therapy, particularly for patients who are intolerant of CPAP therapy. The guidelines emphasize that patient evaluation and appliance fitting should be conducted by qualified dentists trained in dental sleep medicine. For optimal outcomes, the use of custom-fitted, titratable OAs is recommended. Additionally, the AADSM advises that patients be offered a trial of OA therapy prior to considering surgical interventions for OSA.

The American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) position statement (2021) on the use of oral appliances for the treatment of OSA recommends OAs as a treatment option for patients with OSA, particularly those who are unable to tolerate CPAP therapy. The AAO-HNS supports the use of custom-fitted OA provided by qualified dental professionals. The Academy emphasizes the importance of interdisciplinary collaboration between otolaryngologists, sleep physicians, and dental sleep medicine providers to ensure optimal patient outcomes. The AAO-HNS encourages ongoing monitoring and follow-up to assess treatment effectiveness and manage potential side effects, such as dental or jaw changes.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates oral appliances as medical devices. All oral appliances including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Sept 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Sept 11]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

CDT Codes

Code	Description
D9947	Custom sleep apnea appliance fabrication and placement (Effective 01/01/22
D9948	Adjustment of custom sleep apnea appliance (Effective 01/01/22)
D9949	Repair of custom sleep appliance (Effective 01/01/22)

HCPCS Codes

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
E0490 (E/I)	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0491 (E/I)	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply

Code	Description
E0492 (E/I)	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
E0493 (E/I)	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
E0530 (E/I)	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type (01/01/24)
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
K1037	Docking station for use with oral device/appliance used to reduce upper airway collapsibility

ICD10 Codes

Code	Description
F51.8	Other sleep disorders not due to a substance or known physiological condition
G47.00-G47.09	Insomnia (code range)
G47.10-G47.19	Hypersomnia (code range)
G47.20-G47.29	Circadian rhythm sleep disorder (code range)
G47.30-G47.39	Sleep apnea (code range)
G47.69	Other sleep related movement disorders
G47.8-G47.9	Other and unspecified sleep disorder (code range)

REFERENCES

American Academy of Dental Sleep Medicine (AADSM) [Internet]. Dental sleep medicine standards for screening, treatment, and management of sleep-related breathing disorders in adults using oral appliance therapy. [updated 2022; accessed 2025 Sept 11]. Available from: https://www.aadsm.org/docs/jdsm.10.10.2022.sa1.pdf

American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) [Internet]. Position statement: Use of oral appliances for the treatment of obstructive sleep apnea (OSA). [updated 2021 Apr 22; accessed 2025 Sept 11]. Available from: https://www.entnet.org/resource/position-statement-use-of-oral-appliances-for-the-treatment-of-obstructive-sleep-apnea-osa/

Baptista PM, et al. Daytime neuromuscular electrical therapy of tongue muscles in improving snoring in individuals with primary snoring and mild obstructive sleep apnea. J Clin Med. 2021 Apr 27;10(9):1883

Beri A, et al. Appliances therapy in obstructive sleep apnoea: a systematic review and meta-analysis. Cureus. 2023 Nov 4;15(11):e48280.

Kotecha B, et al. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. Sleep Breath. 2021 Dec;25(4):2083-2090.

Lim J, et al. Oral appliances for obstructive apnea. Cochrane Database Syst Rev 2008 Aug 12;(1):CD004435.

Ng JH and Yow M. Oral appliances in the management of obstructive sleep apnea. Sleep Med Clin. 2019;14(1):109-118.

Ramar K, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. J Clin Sleep Med. 2015 Jul 15;11(7):773-827.

Rossi A, et al. Clinical evidence in the treatment of obstructive sleep apnoea with oral appliances: a systematic review. Int J Dent. 2021 May 8;2021:6676158.

Uniken Venema JAM, Doff MHJ, Joffe-Sokolova D et al., Long-term obstructive sleep apnea therapy: a 10-year follow-up of mandibular advancement device and continuous positive airway pressure: J Clin Sleep. Med 2020 March 15;16(3) 353-359.

SEARCH TERMS

Obstructive sleep apnea, OSA, Upper Airway Resistance Syndrome

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

LCD - Oral Appliances for Obstructive Sleep Apnea (L33611) [accessed 2025 Sept 11]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
07/02/99, 06/20/01, 03/21/02, 03/20/03, 03/25/04, 04/28/05, 02/23/06, 02/22/07, 02/28/08, 02/26/09, 02/25/10, 02/24/11, 02/27/12, 02/28/13, 02/27/14, 02/26/15, 02/25/16, 04/27/17, 02/22/18, 08/22/19, 10/22/20, 10/28/21, 07/21/22, 08/17/23, 08/22/24, 10/16/25	
Date	**Summary of Changes**
10/16/25	Annual review. Changed policy title to Medical Management of Obstructive Sleep Apnea (OSA). Added new indications for OAs for OSA. Added not medically necessary criteria for the treatment of snoring, central apneas, prefabricated/non-custom oral appliances, and sleep positioning trainers. Updated the replacement time period of medically necessary oral appliance from two (2) years to five (5) years. New codes added to the policy (D9947,D9948, D9949 and E0530).
01/01/25	• Summary of changes tracking implemented.
07/02/99	• Original effective date