

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	ORAL APPLIANCES FOR THE TREATMENT OF SLEEP-RELATED BREATHING DISORDERS
Policy Number	1.01.07
Category	Equipment/Supplies
Effective Date	10/18/01
Revised Date	03/21/02, 3/20/03, 03/25/04, 04/28/05, 02/23/06, 02/22/07, 02/28/08, 02/28/19
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Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare 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.

POLICY STATEMENT

- I. Based upon our criteria and review of peer-reviewed literature, oral appliances for the treatment of clinically documented *mild to moderate obstructive sleep apnea* (Respiratory Disturbance Index [RDI] or Apnea/Hypopnea Index [AHI] of 5-30) have been medically proven to be effective and therefore, **medically appropriate**.
- II. Based upon our criteria and assessment of peer-reviewed literature, oral appliances are considered **medically appropriate** as a treatment option for *severe obstructive sleep apnea* (RDI/AHI greater than 30) when the patient is intolerant of CPAP, is not considered a surgical candidate, or refuses CPAP or surgical intervention.
- III. Based on our criteria and assessment of peer-reviewed literature, oral appliances for the treatment of clinically documented *upper airway resistance syndrome (UARS)* are considered **medically appropriate** as treatment option when attempts at behavioral modification have failed.
- IV. Based upon our criteria and assessment of peer-reviewed literature, oral appliances for the treatment of *primary snoring without evidence of UARS or obstructive sleep apnea (OSA)* are considered **not medically necessary**.

Refer to Corporate Medical Policy #7.01.41 regarding Surgical Management of Sleep Disorders.

Refer to Corporate Medical Policy # 11.01.17 regarding Temporomandibular Joint Disease

POLICY GUIDELINES

- I. Attempts at behavioral modifications and life style changes (e.g., good sleep hygiene, weight loss, avoidance of alcohol consumption in evening, smoking cessation, sleep position change, treatment of nasal congestion) for patients 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 oral appliance should be made by an experienced dentist/orthodontist in collaboration with a sleep specialist

DESCRIPTION

Sleep disordered breathing includes a variety of breathing disturbances that occur during sleep, exemplified by snoring, hypoventilation, apnea, increased upper airway resistance and nocturnal asthma. Primary snoring refers to snoring that is not accompanied by apnea, hypoventilation or excessive sleepiness.

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Obstructive sleep apnea syndrome (OSAS) results from upper airway obstruction and is defined as the cessation of airflow through the nose and mouth for at least 10 seconds with a respiratory effort noted. OSAS has been shown to cause increased morbidity and mortality from cardiovascular complications including hypertension and cardiac arrhythmias. OSAS is characterized by excessive daytime sleepiness, impaired cognition and mood disorders. Mild to moderate OSA is defined as having an Apnea/Hypopnea Index (AHI), or Respiratory Disturbance Index (RDI), of 5 to 30 episodes per hour of sleep during diagnostic laboratory polysomnography (sleep study). A patient with severe OSA has been found to have a RDI or AHI greater than 30.

Upper Airway Resistance Syndrome (UARS) develops because of a relaxation in the throat, which makes it harder to inhale, and increases the work of breathing. The increased respiratory effort exerted by UARS patients during narrowing of the airway causes pressure swings within the chest. These fluctuations in pressure can be measured with esophageal monitoring during a polysomnogram. UARS is characterized by repetitive EEG arousals from sleep, which leads to sleep deprivation and resultant daytime sleepiness and chronic fatigue.

Oral appliances (OA) that treat snoring, upper airway resistance syndrome (UARS) and Obstructive Sleep Apnea (OSA) are devices placed in the mouth and utilized during sleep to prevent the collapse of the upper airway thus maintaining patency to allow adequate ventilation and prevent sleep apneic episodes. These appliances may be used as an alternative to other medical (e.g., continuous positive airway pressure – CPAP) and surgical (e.g., uvulopalatopharyngoplasty – UPPP) interventions for mild to moderate OSA. The most common types of appliances are the Mandibular Repositioning Device and the Tongue Retaining Device.

RATIONALE

The consistency of the findings among studies support the use of oral appliances as an alternative treatment method for patients with sleep-related breathing disorders. A systematic review by J Lim, et al (2006) concluded the following: There is evidence suggesting that OA improves subjective sleepiness and sleep disordered breathing compared with a control. 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. Until there is more definitive evidence on the effectiveness of OA in relation to CPAP, with regard to symptoms and long-term complications, it would appear to be appropriate to recommend OA therapy to patients with mild symptomatic OSAH, and those patients who are unwilling or unable to tolerate CPAP therapy.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
No specific code(s)	

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HCPCS Codes

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

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

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

Policy previously titled "Nocturnal Airway Patency Appliance (NAPA)".

*Almeida FR, et al. Long-term sequella of oral appliance therapy in obstructive sleep apnea patients: Part 1. Cephalometric analysis. *Am J Orthod Dentofacial Orthop* 2006 Feb;129(2):195-204.

*Almeida FR, et al. Long-term sequella of oral appliance therapy in obstructive sleep apnea patients: Part 2. Study-model analysis. *Am J Orthod Dentofacial Orthop* 2006 Feb;129(2):205-13.

Al-Jewair TS, et al. Quality Assessment of Systematic Reviews on the Efficacy of Oral Appliance Therapy for Adult and Pediatric Sleep-Disordered Breathing. *J Clin Sleep Med*. 2016 Aug 15;12(8):1175-83

*American Academy of Sleep Medicine. 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;11(7):773–827. [http://www.aasmnet.org/Resources/clinicalguidelines/Oral_appliance-OSA.pdf] accessed 3/17/17.

*Bloch KE, et al. A randomized, controlled crossover trial of two oral appliances for sleep apnea treatment. *Am J Respir Crit Care Med* 2000 Jul;162(1):246-51.

BlueCross BlueShield Association. Diagnosis and medical management of obstructive sleep apnea syndrome. Medical Policy Reference Manual Policy #2.01.18. 2017 Jun 08.

Carvalho FR, et al. Oral appliances and functional orthopaedic appliances for obstructive sleep apnoea in children. *Cochrane Database Syst Rev* 2016 Oct 5;10:CD005520.

*Chan AS, et al. Dental appliance treatment for obstructive sleep apnea. *Chest* 2007 Aug;132(2):693-9.

*Ferguson KA, et al. Oral appliances for snoring and obstructive sleep apnea: a review. *Sleep* 2006 Feb 1;29(2):244-62.

Giannasi LC, et al. Efficacy of an oral appliance for the treatment of obstructive sleep apnea. *Int J Prosthodont* 2013 Jul-Aug;26(4):334-9.

*Gotsopoulos H, et al. Oral appliance therapy reduces blood pressure in obstructive sleep apnea: a randomized controlled trial. *Sleep* 2004 Aug 1;27 (5):934-41.

Guarda-Nardini L, et al. Anatomically Based Outcome Predictors of Treatment for Obstructive Sleep Apnea with Intraoral Splint Devices: A Systematic Review of Cephalometric Studies. *J Clin Sleep Med*. 2015 Nov 15;11(11):1327-34.

*Hoekema A, et al. Efficacy and co-morbidity of oral appliances in the treatment of obstructive sleep apnea-hypopnea: a systemic review. *Crit Rev Oral Biol Med* 2004 Jun 4;15(3):137-55.

*Hoekema A, et al. Obstructive sleep apnea therapy. *J Dent Res* 2008 Sep;87(9):882-7.

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Johal A, et al. Ready-made versus custom-made mandibular repositioning devices in sleep apnea: a randomized clinical trial. *J Clin Sleep Med*. Feb 15 2017;13(2):175-182.

*Jonas DE, et al. Screening for Obstructive Sleep Apnea in Adults: An Evidence Review for the U.S. Preventive Services Task Force [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2017 Jan. Report No.: 14-05216-EF-1.

U.S. Preventive Services Task Force Evidence Syntheses, formerly Systematic Evidence Reviews.

Kuna ST, et al. Evaluation of an oral mandibular advancement titration appliance. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2006 May;101(5):593-603.

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

Marklund M. et al. Oral appliance therapy in patients with daytime sleepiness and snoring or mild to moderate sleep apnea: a randomized clinical trial. *JAMA Intern Med* 2015 Aug;175(8):1278-85.

Ng AT, et al. Oralpharyngeal collapse predicts treatment response with oral appliance therapy in obstructive sleep apnea. *Sleep* 2006 May 1;29(5):666-71.

Nizankowska-Jędrzejczyk A, et al. Modulation of inflammatory and hemostatic markers in obstructive sleep apnea patients treated with mandibular advancement splints: a parallel, controlled trial. *J Clin Sleep Med* 2014 Mar 15;10(3):255-62.

Phillips CL, et al. Health outcomes of continuous positive airway pressure versus oral appliance treatment for obstructive sleep apnea: a randomized controlled trial. *Am J Respir Crit Care Med* 2013 Apr 15;187(8):879-87.

Sharples L, et al. Clinical effectiveness and cost-effectiveness results from the randomised controlled Trial of Oral Mandibular Advancement Devices for Obstructive sleep apnoea-hypopnoea (TOMADO) and long-term economic analysis of oral devices and continuous positive airway pressure. *Health Technol Assess*. 2014 Oct;18(67):1-296.

Stouder S, et al. Does an oral appliance reduce palatal flutter and tongue base snoring? *Otolaryngol Head Neck Surg* 2007 May;136(5):827-31.

Sutherland K, et al. Oral Appliance Treatment for Obstructive Sleep Apnea: An Update *J Clin Sleep Med*. 2014 Feb 15; 10(2): 215–227

*Key Article

KEY WORDS

Obstructive sleep apnea, OSA, Upper Airway Resistance Syndrome

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently an archived Local Coverage Determination (LCD) and a related Coverage Article addressing Oral Appliances for Obstructive Sleep Apnea. Please refer to the following website for Medicare Members:

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33611&ver=6&Date=&DocID=L33611&bc=iAAAABAAAAAAAAA%3d%3d&>