

## Medical Coverage Policy | Oral Appliances for Sleep Apnea



**EFFECTIVE DATE:** 10|01|2021

**POLICY LAST UPDATED:** 06|16|2021

### OVERVIEW

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. Medical management of OSA may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous positive airway pressure (CPAP) during sleep.

This policy addresses treatment for sleep disorders with dental (oral) appliances.

### PRIOR AUTHORIZATION

Prior authorization review is not required.

### POLICY STATEMENT

#### Medicare Advantage Plans and Commercial Products

Intraoral appliances for use in the treatment of documented mild to moderate obstructive sleep apnea are covered under the member's durable medical equipment service when rendered by doctors trained in oral sleep appliances.

Other oral appliances used to treat conditions such as temporomandibular joint disease (TMJ) or bruxism (grinding or clenching of teeth) are considered non-covered service for all product lines.

Oral appliances for OSA that are available over the counter are not covered as they have not shown to be as effective as custom-fitted oral appliances in the treatment of OSA.

Nasal expiratory positive airway pressure and oral pressure therapy, palate and mandible expansion devices are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Devices for the treatment of snoring, not associated with sleep apnea, are not covered.

### MEDICAL CRITERIA

Not applicable.

### BACKGROUND

Obstructive sleep apnea syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This causes a drop in blood oxygenation and a brief arousal, and can occur as frequently as every minute throughout the night. The most common signs and symptoms in adults are snoring, excessive daytime sleepiness, and hypertension. Excessive daytime sleepiness may be subjective, and is assessed by questionnaires such as the Epworth Sleepiness Scale, a short self-administered questionnaire that asks patients how likely they are to fall asleep in different scenarios such as watching TV, sitting quietly in a car, or sitting and talking to someone. Daytime sleepiness is uncommon in young children with OSA. Symptoms in children may include disturbed sleep and daytime neurobehavioral problems. In otherwise healthy children, OSA is usually associated with adenotonsillar hypertrophy and/or obesity.

A hallmark sign of OSA is snoring. The snoring abruptly ceases during the apneic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. Upper airway resistance syndrome is a variant of OSA that is characterized by a partial collapse of the airway, resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha electroencephalographic (EEG) arousals (“respiratory event-related arousals” [RERAs]). The sleep fragmentation associated with repeated arousal during sleep can lead to impairment of daytime activity. Adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, i.e., cars, trucks, or heavy equipment. OSA in children may result in neurocognitive impairment and behavioral problems.

OSA can also affect the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to daytime sleepiness. It is estimated that about 7% of adults have moderate or severe OSA, and 20% have at least mild OSA and that the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease.

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure (PAP) therapy (i.e., fixed CPAP, bilevel PAP [BiPAP], or auto-adjusting positive airway pressure [APAP]) during sleep.

Oral appliances can be broadly categorized as mandibular advancing/positioning devices or tongue-retaining devices. Oral appliances can either be “off the shelf” or custom made for the patient by a dental laboratory or similar provider.

Following appropriate radiological examinations, the oral device should be fitted by personnel trained and experienced in the overall management of oral health. To ensure the therapeutic benefit of the appliance, the patient should undergo follow-up examinations, adjustments of the device, and a follow-up polysomnography. The appliances themselves are categorized by Medicare as durable medical equipment (DME) and are not dental devices.

A systematic review of the evidence on the treatment of OSA with oral appliance therapy showed that oral appliances had no significant effect on sleep architecture and sleep efficiency. Meta-analysis found CPAP to be more effective than oral appliances, supporting the use of CPAP as a first-line therapy for treating OSA.

### **Nasal Expiratory Positive Airway Pressure, Oral Pressure Therapy, Sleep Positioning Trainer with Vibration and Daytime Electrical Stimulation of the Tongue**

The Daytime-Nighttime Appliance (DNA Appliance) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance) are customized palate and mandible expanding devices. In addition to the upper-jaw device that is common to both the DNA Appliance and the mRNA Appliance (worn both during the day and night), the mRNA Appliance moves the mandible forward and is worn during sleep. The DNA Appliance and mRNA Appliance systems use 3-dimensional axial springs, which are proposed to gradually expand the upper and lower jaw and airway to treat and eventually eliminate mild-to-moderate OSA.

eXciteOSA (Signifier Medical Technologies) uses daytime stimulation of the tongue to increase muscle tone with the goal of reducing snoring and mild sleep apnea.

NightBalance Sleep Positioning Trainer (Phillips) provides vibration whenever an individual with positional OSA is supine in order to trigger a change in body position.

Other devices that are being marketed for the treatment of OSA are PROVENT and Winx™. PROVENT is a single use nasal expiratory resistance valve device containing valves that are inserted into the nostrils and secured with adhesive. The Winx™ system uses oral pressure therapy (OPT) for the treatment of OSA. OPT provides light negative pressure to the oral cavity by using a flexible mouthpiece connected to a bedside console that delivers negative pressure. This device is proposed to increase the size of the retropalatal airway by pulling the soft palate forward and stabilizing the base of the tongue.

For individuals who have OSA who receive novel OSA treatments (eg, palate expansion, EPAP, oral pressure therapy, tongue stimulation, supine vibration), the evidence includes RCTs, prospective single arm studies, and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on nasal EPAP devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the Apnea/Hypopnea Index (AHI), with minor impact on oxygenation, and a decrease in Epworth Sleepiness Scale (ESS) score. One small RCT with 22 patients found no benefit of an oral EPAP therapy device when added to an oral appliance. One comparative trial with historical controls and a retrospective chart review evaluated daytime sleep study (PAP-NAP) to reduce resistance to CPAP titration or use. Additional study is needed to evaluate the efficacy of this intervention. Single arm studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is uncertain. Several RCTs have been published with a sleep positioning device that vibrates when the individual is in a supine position. Drop-out rates were high and long-term compliance is unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for the applicable “Medical Equipment, Medical Supplies, and Prosthetic Devices, Diagnostic Imaging, Lab, and Machine Tests” benefit/coverage.

The fitting of the appliance and the appliance itself will be provided by a dentist/orthodontist who is experienced in the making of these devices.

### **Note:**

The following services associated with the oral appliance are considered inclusive in the global fee for the device:

- Initial evaluation\*
- Oral/dental impressions
- Fabrication of the appliance
- Initial fitting, patient education, and teaching of use of the device
- Three follow-up visits once patient has begun to use the device\*\*

\*For individuals who are found not to be appropriate candidates for the appliance following the initial consultation, the provider may file for the appropriate evaluation and management code for the assessment of that patient.

\*\*Additional visits, after the three follow-up visits, are the responsibility of the member unless an additional device is supplied.

A set of cephalometric X-rays (with and without the appliance) may be billed separately and are reimbursable. These services will be provided as diagnostic testing services.

The member will be responsible for any applicable durable medical equipment (DME) benefit copayments, coinsurance, and/or deductibles.

There is no waiting period for an oral appliance when a member has a CPAP.

### **Replacement and Repairs**

Replacement appliances and repairs are covered as medically necessary according to the “Durable Medical Equipment Repair and Replacement” policy. Medical review/preauthorization is not required for repair/replacement as the initial services do not require medical review/preauthorization.

### **CODING**

#### **Medicare Advantage Plans and Commercial Products**

The oral device is billable under the following HCPCS code(s):

**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

The following code(s) can be used for the oral interface used with oral pressure therapy devices and is **not medically necessary**:

**A7047** Oral interface used with respiratory suction pump, each

The above HCPCS code(s) for the oral interface is used with devices such as the Winx system.

For any other devices without a specific code(s), claims should be filed with the applicable unlisted code.

The following code(s) is **not medically necessary**:

**K1001** Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type

At this time, there is no specific HCPCS code for the non-invasive tongue stimulator. Claims must be filed with the following unlisted DME code.

**E1399** Durable Medical Equipment, Miscellaneous

### **RELATED POLICIES**

Durable Medical Equipment

### **PUBLISHED**

Provider Update, August 2021

Provider Update, August 2020

Provide Update, January 2020

Provider Update, January 2019

Provider Update, December 2017

### **REFERENCES**

1. Somers VK, White DP, Amin R, et al. Sleep apnea and cardiovascular disease: an American Heart Association/American College Of Cardiology Foundation Scientific Statement from the American Heart Association Council for High Blood Pressure Research Professional Education Committee, Council on Clinical Cardiology, Stroke Council, and Council On Cardiovascular Nursing. In collaboration with the National Heart, Lung, and Blood Institute National Center on Sleep Disorders Research (National Institutes of Health).

Circulation. Sep 2 2008;118(10):1080-1111. PMID 18725495

2. Kushida CA, Littner MR, Morgenthaler T, et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. *Sleep*. Apr 1 2005;28(4):499-521. PMID 16171294
3. Berry RB, Budhiraja R, Gottlieb DJ, et al. Rules for scoring respiratory events in sleep: update of the 2007 AASM Manual for the Scoring of Sleep and Associated Events. Deliberations of the Sleep Apnea Definitions Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med*. Oct 15 2012;8(5):597-619. PMID 23066376
4. Balk EM, Moorthy D, Obadan NO, et al. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32 (AHRQ Publication No. 11-EHC052-EF). Rockville, MD: Agency for Healthcare Research and Quality; Jul 2011.
5. Mulgrew AT, Fox N, Ayas NT, et al. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. *Ann Intern Med*. Feb 6 2007;146(3):157-166. PMID 17283346
6. Senn O, Brack T, Russi EW, et al. A continuous positive airway pressure trial as a novel approach to the diagnosis of the obstructive sleep apnea syndrome. *Chest*. Jan 2006;129(1):67-75. PMID 16424414
7. Berry RB, Hill G, Thompson L, et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. *Sleep*. Oct 1 2008;31(10):1423-1431. PMID 18853940
8. Centers for Medicare and Medicaid Services (CMS). Coverage Decision Memorandum for Sleep Testing for Obstructive Sleep Apnea (OSA) 100-3, Change request 6543. 2009; <http://www.cms.gov/transmittals/downloads/R103NCD.pdf>. Accessed October 3, 2016.
9. Pepin JL, Tamisier R, Borel JC, et al. A critical review of peripheral arterial tone and pulse transit time as indirect diagnostic methods for detecting sleep disordered breathing and characterizing sleep structure. *Curr Opin Pulm Med*. Aug 29 2009;15(6):550-558. PMID 19724229
10. Pittman SD, Pillar G, Berry RB, et al. Follow-up assessment of CPAP efficacy in patients with obstructive sleep apnea using an ambulatory device based on peripheral arterial tonometry. *Sleep Breath*. Sep 2006;10(3):123-131. PMID 16586136
11. Pang KP, Gourin CG, Terris DJ. A comparison of polysomnography and the WatchPAT in the diagnosis of obstructive sleep apnea. *Otolaryngol Head Neck Surg*. Oct 2007;137(4):665-668. PMID 17903588
12. Penzel T, Kesper K, Pinnow I, et al. Peripheral arterial tonometry, oximetry and actigraphy for ambulatory recording of sleep apnea. *Physiol Meas*. Aug 2004;25(4):1025-1036. PMID 15382839
13. Pittman SD, Ayas NT, MacDonald MM, et al. Using a wrist-worn device based on peripheral arterial tonometry to diagnose obstructive sleep apnea: in-laboratory and ambulatory validation. *Sleep*. Aug 1 2004;27(5):923-933. PMID 15453551
14. Collop NA, Anderson WM, Boehlecke B, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. Portable Monitoring Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med*. Dec 15 2007;3(7):737-747. PMID 18198809
15. Ayappa I, Norman RG, Seelall V, et al. Validation of a self-applied unattended monitor for sleep disordered breathing. *J Clin Sleep Med*. Feb 15 2008;4(1):26-37. PMID 18350959
16. Fox N, Hirsch-Allen AJ, Goodfellow E, et al. The impact of a telemedicine monitoring system on positive airway pressure adherence in patients with obstructive sleep apnea: a randomized controlled trial. *Sleep*. Apr 2012;35(4):477-481. PMID 22467985
17. Berry RB, Parish JM, Hartse KM. The use of auto-titrating continuous positive airway pressure for treatment of adult obstructive sleep apnea. An American Academy of Sleep Medicine review. *Sleep*. Mar 15 2002;25(2):148-173. PMID 11902425
18. Littner M, Hirshkowitz M, Davila D, et al. Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome. An American Academy of Sleep Medicine report. *Sleep*. Mar 15 2002;25(2):143-147. PMID 11902424
19. Kushida CA, Morgenthaler TI, Littner MR, et al. Practice parameters for the treatment of snoring and Obstructive Sleep Apnea with oral appliances: an update for 2005. *Sleep*. Feb 1 2006;29(2):240-243. PMID 16494092

20. Morgenthaler TI, Aurora RN, Brown T, et al. Practice parameters for the use of autotitrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome: an update for 2007. An American Academy of Sleep Medicine report. *Sleep*. Jan 1 2008;31(1):141-147. PMID 18220088
21. Hussain SF, Love L, Burt H, et al. A randomized trial of auto-titrating CPAP and fixed CPAP in the treatment of obstructive sleep apnea-hypopnea. *Respir Med*. Apr 2004;98(4):330-333. PMID 15072173
22. Marrone O, Resta O, Salvaggio A, et al. Preference for fixed or automatic CPAP in patients with obstructive sleep apnea syndrome. *Sleep Med*. May 2004;5(3):247-251. PMID 15165530
23. Stammnitz A, Jerrentrup A, Penzel T, et al. Automatic CPAP titration with different self-setting devices in patients with obstructive sleep apnoea. *Eur Respir J*. Aug 2004;24(2):273-278. PMID 15332397
24. McEvoy RD, Antic NA, Heeley E, et al. CPAP for prevention of cardiovascular events in obstructive sleep apnea. *N Engl J Med*. Sep 8 2016;375(10):919-931. PMID 27571048
25. Mutter TC, Chateau D, Moffatt M, et al. A matched cohort study of postoperative outcomes in obstructive sleep apnea: could preoperative diagnosis and treatment prevent complications? *Anesthesiology*. Oct 2014;121(4):707-718. PMID 25247853
26. Ramar K, Dort LC, Katz SG, 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*. Jul 2015;11(7):773-827. PMID 26094920
27. Johal A, Haria P, Manek S, 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. PMID 27784410
28. Singh GD, Griffin T, Cress SE. Biomimetic oral appliance therapy in adults with severe obstructive sleep apnea. *J Sleep Disord Ther*. 2016;5:1. PMID
29. Singh GD, Cress SE. Biomimetic oral appliance therapy in adults with mild to moderate obstructive sleep apnea using combined maxillo-mandibular correction. *J Sleep Disord Manag*. 2017;3:014. PMID
30. Krakow B, Ulibarri V, Melendrez D, et al. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia patients with sleep disordered breathing to positive airway pressure (PAP-NAP). *J Clin Sleep Med*. Jun 15 2008;4(3):212-222. PMID 18595433
31. Berry RB, Kryger MH, Massie CA. A novel nasal expiratory positive airway pressure (EPAP) device for the treatment of obstructive sleep apnea: a randomized controlled trial. *Sleep*. Apr 2011;34(4):479-485. PMID 21461326
32. Kryger MH, Berry RB, Massie CA. Long-term use of a nasal expiratory positive airway pressure (EPAP) device as a treatment for obstructive sleep apnea (OSA). *J Clin Sleep Med*. Oct 15 2011;7(5):449-453B. PMID 22003339
33. Riaz M, Certal V, Nigam G, et al. Nasal expiratory positive airway pressure devices (Provent) for OSA: a systematic review and meta-analysis. *Sleep Disord*. 2015;2015:734798. PMID 26798519
34. Kureshi SA, Gallagher PR, McDonough JM, et al. Pilot study of nasal expiratory positive airway pressure devices for the treatment of childhood obstructive sleep apnea syndrome. *J Clin Sleep Med*. 2014;10(6):663-669. PMID 24932147
35. Polysomnography Task Force - American Sleep Disorders Association Standards of Practice Committee. Practice parameters for the indications for polysomnography and related procedures *Sleep*. Jun 1997;20(6):406- 422. PMID 9302725
36. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. Mar 15 2017;13(3):479-504. PMID 28162150
37. Epstein LJ, Kristo D, Strollo PJ, Jr., et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. Jun 15 2009;5(3):263-276. PMID 19960649
38. Aurora RN, Zak RS, Karipott A, et al. Practice parameters for the respiratory indications for polysomnography in children. *Sleep*. Mar 2011;34(3):379-388. PMID 21359087
39. Section on Pediatric Pulmonology - Subcommittee on Obstructive Sleep Apnea Syndrome. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. Apr 2002;109(4):704-712. PMID 11927718

40. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. Sep 2012;130(3):576-584. PMID 22926173
41. Qaseem A, Dallas P, Owens DK, et al. Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Aug 5 2014;161(3):210-220. PMID 25089864
42. Qaseem A, Holty JE, Owens DK, et al. Management of obstructive sleep apnea in adults: A clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Oct 1 2013;159(7):471-483. PMID 24061345
43. Spencer J, Patel M, Mehta N, et al. Special consideration regarding the assessment and management of patients being treated with mandibular advancement oral appliance therapy for snoring and obstructive sleep apnea. *Cranio*. Jan 2013;31(1):10-13. PMID 23461257
44. American Society of Metabolic and Bariatric Surgery (ASMBS) Clinical Issues Committee. Peri-operative management of obstructive sleep apnea. *Surg Obes Relat Dis*. May-Jun 2012;8(3):e27-32. PMID 22503595
45. Roland PS, Rosenfeld RM, Brooks LJ, et al. Clinical practice guideline: Polysomnography for sleep-disordered breathing prior to tonsillectomy in children. *Otolaryngol Head Neck Surg*. Jul 2011;145(1 Suppl):S1-15. PMID 21676944
46. Chowdhuri S, Quan SF, Almeida F, et al. An official American Thoracic Society research statement: impact of mild obstructive sleep apnea in adults. *Am J Respir Crit Care Med*. May 1 2016;193(9):e37-54. PMID 27128710
47. U.S. Preventive Services Task Force, Bibbins-Domingo K, Grossman DC, et al. Screening for obstructive sleep apnea in adults: US Preventive Services Task Force Recommendation Statement. *JAMA*. Jan 24 2017;317(4):407-414. PMID 28118461
48. Jonas DE, Amick HR, Feltner C, et al. Screening for obstructive sleep apnea in adults: evidence report and systematic review for the US Preventive Services Task Force. *JAMA*. Jan 24 2017;317(4):415-433. PMID 28118460
49. Centers for Medicare and Medicaid Services (CMS). Pub 100-03 Medicare National Coverage Determinations, Change request 6048. 2008; <http://www.cms.hhs.gov/Transmittals/Downloads/R96NCD.pdf>. Accessed October 3, 2016.
50. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (240.4). 2008; <https://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?MCDId=16&ExpandComments=n&McdName=Thomson+Micromedex+DrugDex+%C2%AE+Compendium+Revision+Request+-+CAG-00391&mcdtypename=Compendia&MCDIndexType=6&NCDId=226&ncdver=3&bc=BAIAAAAAQAAA%3D%3D&>. Accessed June 14, 2017.

**CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS**

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

