

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: MP.063.MH
Last Review Date: 05/27/2021
Effective Date: 08/01/2021

MP.063.MH – Oral Appliances for Obstructive Sleep Apnea

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Oral Appliances for Obstructive Sleep Apnea (OSA)** medically necessary for the following indications:

Custom-fit oral appliances for OSA are considered medically necessary when all of the following are met:

1. The member had a face-to-face clinical evaluation by the treating physician (MD or DO) prior to the sleep test to assess the member for obstructive sleep apnea testing
And
2. The member had a covered sleep test that meets *one* of the following indications:
 - The Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 apneic events per hour with a minimum of 30 total events over the duration of sleep test; or
 - The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of ten total events over the duration of sleep test and documentation of:
 - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia, or
 - Hypertension, ischemic heart disease, or history of stroke; or
 - The AHI is > 30 events or the RDI is > 30 and meets either of the following:
 - Member is not able to tolerate a positive airway pressure (PAP) device; or
 - Treating physician determines the use of a PAP device is contraindicated
And
3. A physician specialist certified in sleep medicine must confirm the diagnosis of OSA and recommend an oral appliance to the treating physician when appropriate;
And
4. The device is ordered by the treating physician following review of the report of the sleep test. (Note: The physician who provides the order for the oral appliance could be either the sleep medicine specialist or the one who performed clinical evaluation.)
And

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5. The device is provided for and billed by a licensed dentist. (DDS- Doctor of Dental surgery or DMD- Doctor of Dental Medicine)

Follow-Up Care

Includes fitting, adjustments, modifications, and professional services:

- During the first 90 days after provision of the oral appliance, fittings, adjustments, modifications, and follow-up visits are considered to be included in the initial payment for the device.
- After the initial 90 day period, adjustments, modifications, and follow-up visits are not eligible for coverage.

Repairs

- Oral appliance repairs are covered:
 - For items that meet the coverage indications
 - When it is necessary to make the item serviceable
- If the expense for repairs exceeds the estimated expense of purchasing another item, no payment can be made for the excess

Replacement

Oral appliances are eligible for replacement at the end of their five year reasonable useful lifetime (RUL). These items may be replaced prior to the end of the five year RUL in cases of loss, theft, or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g. fire, flood). Replacement due to wear-and-tear as the result of everyday use will not be covered prior to the expiration of the five year RUL.

Limitations

1. Dentists who render therapy with oral appliances for OSA must have thorough knowledge and skill levels related to diagnosis and management of sleep related breathing disorders.
2. Dentists who supply custom oral appliances must be accredited as Durable Medical equipment (DME) provider.
3. All sleep tests must be interpreted by a physician specialist in sleep medicine who holds at least one of the following:
 - Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or
 - Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or
 - Completed residency or fellowship training in a program approved by an ABMS member board and has completed all the requirements for subspecialty

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certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or

- Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO)

4. **Not Covered** - considered not medically necessary

- Prefabricated oral appliances- there is insufficient evidence to show that these are items are effective therapy for OSA
- Over-the-counter oral appliances
- Custom fabricated appliances that achieve their effect through positioning of the tongue
- Oral appliances used as a treatment for snoring without a diagnosis of OSA (Examples: Silent Nite, SnoreAid , Therasnore)
- Oral appliances used to treat dental conditions
- Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders of the jaw are considered dental-related

5. **Experimental/Investigational** and therefore not covered

- Combination Therapy, such as TAP-PAP
- Winx device (Winx TM Sleep Therapy System) by ApniCure

Background

Apnea is defined as the cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the AHI. Sleep time can only be measured in a Type I (facility-based polysomnogram) or Type II sleep study.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes

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

ICD-10 codes covered if selection criteria are met:

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G47.33	Obstructive Sleep Apnea (adult, pediatric)
Non Covered Codes	
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, pre-fabricated includes fitting and adjustment.

References

1. Centers for Medicare and Medicaid Services (CMS) Local Coverage Determination (LCD) No. L33611. Oral appliances for obstructive sleep apnea. Revision Effective Date: 01/01/2020. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33611&ver=20&bc=CAAAAAAAAAAAAA>
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L33718. Positive airway pressure devices for the treatment of obstructive sleep apnea. Revision Effective Date: 01/01/2020. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33718&ver=20&bc=CAAAAAAAAAAAAA>
3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article No. A52512- Oral appliances for obstructive sleep apnea- Policy Article. Revision Effective Date: 04/03/2020. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52512&ver=22&Date=&DocID=A52512&bc=hAAAABAAA&AAA&>
4. Department of Health and Human Services. Agency for Healthcare Research and Quality. (AHRQ). National Guideline Clearinghouse (NGC). Management of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. NGC# 10028. Last updated: Dec. 12, 2013. <https://www.ncbi.nlm.nih.gov/pubmed/24061345>
5. Hoffstein V. Review of oral appliances for treatment of sleep-disordered breathing. Sleep Breath. 2007 Mar;11(1):1-22. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1794626/pdf/11325_2006_Article_84.pdf
6. Lee CH, Mo JH, Choi IJ, et al. The mandibular advancement device and patient selection in the treatment of obstructive sleep apnea. Arch Otolaryngol Head neck Surg. 2009 May;135(5):439-44. doi: 10.1001/archoto.2009.31. <http://www.ncbi.nlm.nih.gov/pubmed/19451462>
7. Phillips CL, Grunstein RR, Darendeliler MA, 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. doi: 10.1164/rccm.201212-2223OC. <http://www.ncbi.nlm.nih.gov/pubmed/23413266>

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8. Sleep Review: Oral Appliances Side-by-Side Comparison Guide (December 2013). <http://www.sleepreviewmag.com/2014/01/oral-appliances-side-by-side-comparison-guide-december-2013/>. Full matrix: <http://cdn.sleepreviewmag.com/sleeprev/2014/01/1213OralAppliances.pdf>

Archived References

1. Hayes Medical Technology Directory. Sleep Apnea Treatment, Devices. March 14, 2005. Archived Date: January 1, 2006.

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

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