MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

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

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers Oral Appliances for Obstructive Sleep Apnea 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

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 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 ™ 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-9 codes covered if selection criteria are met:	
327.23	Obstructive Sleep Apnea (adult, pediatric)
ICD-10 codes covered if selection criteria are met:	
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.

Variations
Medicare Advantage Products

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
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
- If the AHI is > 30 events per hour or the RDI is > 30 events per hour and meets one of the following:
- The patient is not able to tolerate a PAP device

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

References

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9. 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

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