



**Subject:** *Oral Devices for Obstructive Sleep Apnea*

**Number:** *200312-0006*

Effective date: 12/29/2003

Revision date(s): 04/2001, 06/2001, 06/2003, 12/18/2003

**Important note**

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the *Evidence of Coverage* to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy and Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. The Centers for Medicare and Medicaid's *Coverage Issues Manual* can be found on the following Web site: <http://www.cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

**Overview**

This policy is specific to the types of **oral devices** used to treat obstructive sleep apnea (OSA). This type of intra-oral device modifies the patient's airway by changing the posture of the mandible and tongue.

These devices have been shown to be effective in alleviating OSA, and present a useful alternative to CPAP or surgery. However, they have been shown to be less reliable and effective than CPAP. Therefore, it is suggested in the literature that their use be reserved for patients who do not tolerate CPAP.

Oral devices or appliances for OSA are considered durable medical equipment (DME) and are applied towards the DME benefit limit.

**Policy and criteria**

**NOTE:** These services require prior authorization by the plan medical director.

**When services are covered:**

We cover **oral devices** approved by the Food & Drug Administration for the treatment of OSA when ALL of the following criteria are met:

- Confirmed diagnosis of moderate to severe sleep apnea defined as results of a polysomnography test conducted within the previous 12 months that documents a Respiratory Disturbance Index (RDI) or Apnea Hypopnea Index (AHI) of:
  - $\geq 15$ ; *or*
  - $>5$  and  $\leq 14$  with at least one of the following:
    - oxygen saturation below 85%; *or*
    - excessive daytime sleepiness; *or*
    - documented hypertension of  $> 140/90$  and/or hypertensive cardiovascular disease

AND

- previous trial of CPAP was attempted and the patient did not tolerate it or it was not effective;

AND

- documentation of adequate dentition to anchor the device of:
  - at least 7 mm of protrusive jaw movement; *and*
  - free of temporomandibular joint pathology;

AND

- a reasonable expectation that the oral device will work

The formula for RDI or AHI is as follows:

$$\text{RDI/AHI} = \frac{\text{(total number of apneas + hypopneas, including subtle hypopneas)}}{\text{total number of sleep hours}}$$

Apnea Index (AI) – an alternative to RDI/AHI – is calculated using the following formula:

$$\text{AI} = \frac{\text{(total number of apneas)}}{\text{total number of sleep hours}}$$

***When services are not covered:***

We **do not cover** services when the above criteria are not met **or for any procedures or devices not listed above.**

We **do not cover** services if one or more of the following contraindications exist:

- body mass index (BMI) of  $\geq 35$
- neck size over 20 inches
- fewer than nine teeth in either arch
- a history of significant TMJ pain or discomfort
- a growing child
- a restricted oral opening of  $< 33\text{mm}$  between the edges of the upper and lower front teeth when the patient opens as much as possible
- severe hypoxemia\*
- evidence of abnormal nasal passages or obstructed nasal airway.

**\*Note:** Oral appliances are generally not recommended for treatment of severe OSA.

We **do not cover** services for the treatment of snoring alone when there is no diagnosis of OSA. The treatment of snoring is not medically necessary and is, therefore, not covered. This includes, but may not be limited to, oral or tongue retaining devices.

We **do not cover** services related to dental rehabilitation, including but not limited to dentures, bridgework, dental prosthetics and/or implants, as treatment for OSA. These are considered dental and not medical services and are, therefore, not usually covered.

We **do not cover** oral devices or appliances for OSA that are available over-the-counter (OTC) or without a prescription. OTC items are listed as a specific exclusion in the member materials.

**Codes:**

Codes	Number	Description
CPT	none	
HCPCS	S8260	Oral orthotic for treatment of sleep apnea, includes fitting, fabrication, and materials

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**FCHP products to which this policy applies:**

- ⊕ FCHP Direct and FCHP Select Care (HMO)
- ⊕ FCHP Flex Care Direct and Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ FCHP MassHealth
- ⊕ Non-Group: FCHP Independent Care, Direct enrollment and Bill-at-home
- ⊕ Medicare plan – *reminder* to refer to CMS for policy and criteria

**References**

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3. Ferguson KA, Ono T, Lowe AA, Keenan SP, Fleetham JA. A randomized crossover study of an oral appliance vs nasal-continuous positive airway pressure in the treatment of mild-moderate obstructive sleep apnea. *Chest*. 1996 May;109(5):1269-75.
4. Hayes, Winifred S. Technology Report. Sleep Apnea Treatment, Devices. August 1999. Updated April 2003.
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7. Randerath WJ, Heise M, Hinz R, Ruehle KH. An individually adjustable oral appliance vs continuous positive airway pressure in mild-to-moderate obstructive sleep apnea syndrome. *Chest* 2002 Aug;122(2):569-75.
8. Rogers RR. A Review of Oral Appliance Therapy in Sleep Populations. *Sleep Review*, Fall 2000, 40-45.
9. Schmidt-Nowara W, Lowe A, Wiegand L, et al. Oral appliances for the treatment of snoring and obstructive sleep apnea: An American Sleep Disorders Association Review. *Sleep*. 1995;18(6):501-510.

**Mandated benefit/Regulatory issues**

- ∅ Federal
- ∅ Commonwealth of Massachusetts
- ⊕ Medicare – National Policy
- ∅ Medicare – Local Medical Review Policy
- ∅ Not applicable

**Committee review dates:**

**Technology Assessment Committee:** 04/2001, 06/2001

**Utilization Management Committee:** 06/2003

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Approved by: *Signature on file* 12/29/2003  
Dennis A. Batey, M.D. VP& Chief Medical Officer Date