



**ORAL APPLIANCES FOR
OBSTRUCTIVE SLEEP APNEA
HS-057**



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

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WellCare Prescription Insurance, Inc.

**Oral Appliances for
Obstructive Sleep Apnea**

Policy Number: HS-057

Original Effective Date: 11/6/2008

**Revised Date(s): 11/11/2009;
11/12/2010; 10/6/2011**

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Sleep apnea syndrome (SAS) is a sleep-related breathing disorder defined as the cessation of breathing for an interval of > 10 seconds recurring repetitively (> 10 times per hour) throughout sleep. During sleep, upper airway muscle tone and resistance decrease and increase, respectively, causing collapse of the upper airway. This collapse leads to total obstruction (apnea) or partial obstruction (hypopnea) of the upper airway, resulting in decreased arterial oxygen saturation (SaO₂) and disruption in normal sleep architecture. While anyone may experience apneic episodes, the frequency and duration of these episodes increase in the presence of a variety of anatomic and functional abnormalities that result in decreased upper airway space, respiratory strength, or ventilatory drive. In general, SAS is categorized according to its cause. Obstructive sleep apnea (OSA) is caused by reduced upper airway space due to the normal sleep-related collapse of the upper airway, as well as abnormalities that further reduce upper airway space.

Nasal continuous positive airway pressure (CPAP or nCPAP), is considered the standard of care for treatment of SAS. However, a sizable number of apnea patients cannot tolerate the device, and compliance rates are correspondingly low. Several modifications to traditional CPAP, as well as a number of other alternative nonsurgical devices have been proposed.

Devices have been created to be used either in patients with mild disease who cannot tolerate CPAP or who have not responded to or are not suitable candidates for surgery. The literature indicates that most of these devices are relatively free of serious side effects in most patient populations and produce acceptable reductions among outcome parameters, such as the apnea/hypopnea index (AHI). Dental prosthetic devices have recently gained popularity as a treatment for OSA. This popularity is partially due to the ease of using the dental device and to poor tolerance and compliance often associated with CPAP use. Several different intraoral devices can be used to treat OSA. They can be divided into two groups: (1) those that hold the tongue forward during sleep (tongue-retaining devices); (2) and those that advance the mandible (anterior mandibular positioning or mandibular advancement devices). The other common form of OSA treatment is a mandibular repositioning appliance which is believed to act by advancing the mandible and increasing upper airway size. It has recently been shown that prosthetic appliances used in the treatment of OSA activate masticatory and tongue muscles during sleep to prevent the upper airway from collapsing (from Hayes, 1999).

POSITION STATEMENT

An oral appliance is considered medically necessary if ALL of the following criteria are met:

- 1) The member has a clinical evaluation by the treating physician (MD or DO) before the performance of a sleep test to assess the member for obstructive sleep apnea; **AND**,
- 2) The member has a sleep test* that confirms that:
 - a. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal 15 events per hour with a minimum of 30 events; **OR**;
 - b. The AHI or RDI is greater than or equal to 5 events and less than or equal to 14 events per hour with a minimum of 10 events total and documentation of:
 - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **OR**,
 - Hypertension, ischemic heart disease, or history of stroke.

AND,

- 3) The member is not able to tolerate a positive airway pressure device or the treating physician determines

that the use of said device is contraindicated.

*** Sleep Test Requirements**

The sleep test performed **must be** a:

- 1) Polysomnogram performed in a facility-based laboratory (Type I)

A Type I sleep test is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It is facility-based and must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), and electro-oculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

Follow-Up

To ensure satisfactory therapeutic benefit for the appliance, the member should undergo polysomnography with the oral appliance in place after final adjustments of fit have been performed.

Once optimal fit is obtained and efficacy shown, dental specialist follow up every 6 months is recommended for the first year, and at least annually thereafter.

Members with obstructive sleep apnea who are treated with oral appliances should return for follow-up visits with the referring physician to assess the member for current severity of signs and symptoms of obstructive sleep apnea.

CODING

CPT®* Codes No applicable codes

CD-9-CM Procedure Codes No applicable codes

Covered HCPCS Level II ® Codes

- E0485** Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
- E0486** Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment

Covered ICD-9-CM Diagnosis Codes

- 327.23** Obstructive sleep apnea (adult) (pediatric)

*Current Procedural Terminology (CPT) 2011 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Hayes Directory. (1999, September 16). Sleep apnea treatment: devices. Retrieved from <http://www.hayesinc.com>
2. Kushida, C.A., Morgenthaler, T.I., Littner, M.R., Alessi, C.A., Bailey, D., Coleman, J., & et al. (2006). Practice

parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005. *Sleep*, 29(2), 240-243.

Government Agencies, Professional and Medical Organizations

1. ~~Centers for Medicare and Medicaid Services. Local coverage determination for oral appliances for obstructive sleep apnea (DL28620). Delete; no longer on CMS website. Final LCD # L28620 Oral Appliances for Obstructive Sleep Apnea~~

HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
10/6/2011	<ul style="list-style-type: none">• Approved by MPC. Reformatted references (delete one); no major changes. Reformatted references (delete one); no major changes. Added to References Final LCD # L28620 <i>Oral Appliances for Obstructive Sleep Apnea</i>. (DL28620 was a <u>Draft</u> LCD in 2010, L28620 is the Final). Delete Code S8262 for 2011 as not applicable.