

## Medical Coverage Policy | Oral Appliances for Sleep Apnea



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**POLICY LAST UPDATED:** 11 | 15 | 2016

### 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

#### BlueCHiP for Medicare 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.

Other oral appliances used to treat conditions such as temporomandibular joint disease (TMJ) or bruxism (grinding or clenching of teeth) are considered a contract exclusion (a 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 (EPAP) and oral pressure therapy devices are considered not medically necessary as there is no peer reviewed published literature to support if efficacy.

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 and Oral Pressure Therapy**

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.

The evidence on EPAP devices in patients with OSA is lacking and additional study is needed to evaluate the efficacy of this intervention with greater certainty. Therefore, EPAP is considered not medically necessary.

No evidence was identified on the oral therapy device. The evidence is insufficient to determine the effects of the technology on health outcomes, and is considered not medically necessary.

## **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**

**BlueCHiP for Medicare and Commercial Products**

The oral device is billable under the following HCPCS codes:

**E0485**

**E0486**

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

**A7047**

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

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

**RELATED POLICIES**

Durable Medical Equipment

## PUBLISHED

Provider Update, January 2017  
Provider Update, April 2015  
Provider Update, June 2008  
Policy Update, September 2007  
BCBSRI.com, July 2007

## REFERENCES

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