Medical Coverage Policy | Oral Appliances for Sleep Apnea

EFFECTIVE DATE: 04|15|2008
POLICY LAST UPDATED: 01|20|2015

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 during sleep.

This policy addresses treatment for sleep disorders with dental appliances.

PRIOR AUTHORIZATION

Prior authorization review is not required.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

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

The hallmark symptom of OSA is excessive daytime sleepiness; the hallmark clinical sign 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. Sleep fragmentation associated with repeated arousal during sleep can lead to impairment of daytime activity. For example, adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, ie, cars, trucks, or heavy equipment. OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects 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.

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. A number of oral appliances have received marketing clearance through the 510(k) pathway (product code LQZ) for the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™, Lamberg SleepWell-Smarttrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, Desra, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device.

Following appropriate radiological examinations, the 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.

In 2010, a nasal expiratory resistance valve (PROVENT®, Ventus Medical) received marketing clearance through the U.S. Food and Drug Administration's (FDA) 510(k) for the treatment of OSA. PROVENT is a single use device containing valves that are inserted into the nostrils and secured with adhesive. The Winx™ system, which uses oral pressure therapy (OPT) for the treatment of OSA, received marketing clearance in 2012. 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.
No full-length, peer-reviewed studies on oral pressure therapy have been identified in the published literature. Therefore, it is not possible to evaluate the efficacy of this treatment based on scientific evidence and the services are considered not medically necessary.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate 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 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
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

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	Apr	2015
Provider Update	Jun	2008
Policy Update	Sep	2007
BCBSRI.com	Jul	2007

REFERENCES

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2. Lim J, Lasserson TJ, Fleetham J et al. Oral appliances for obstructive sleep apnoea. Cochrane Database Syst Rev 2006; (1):CD004435.
3. Kushida CA, Morgenthaler TI, Littner MR et al. Practice parameters for the treatment of snoring and Obstructive Sleep Apnea with oral appliances: an update for 2005. Sleep 2006; 29(2):240-3.
4. Phillips CL, Grunstein RR, Darendeliler MA et al. Health Outcomes of CPAP versus Oral Appliance Treatment for Obstructive Sleep Apnea: A Randomised Controlled Trial. Am J Respir Crit Care Med 2013.
5. Spencer J, Patel M, Mehta N et al. Special consideration regarding the assessment and management of patients being treated with mandibular advancement oral appliance therapy for snoring and obstructive sleep apnea. Cranio 2013; 31(1):10-3.

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