MEDICAL POLICY – 2.01.532
Intraoral Appliances for the Treatment of Obstructive Sleep Apnea

Effective Date: Apr. 1, 2017
Last Revised: Mar. 14, 2017
Replaces: 2.01.503 (in part)

RELATED MEDICAL POLICIES:
1.01.524 Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea
2.01.503 Polysomnography and Home Sleep Study for Diagnosis of Obstructive Sleep Apnea
7.01.554 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING |RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Sleep apnea is a condition that causes a person to stop breathing for short periods of time during sleep. There are several ways to treat it, including using a specific type of device worn in the mouth (intraoral appliance). This dental appliance slightly moves the tongue and jaw forward, the end result being more air coming into the airway. These appliances look similar to mouth guards to prevent teeth grinding or to realign teeth. This policy describes when an intraoral device for sleep apnea is covered in adults.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
Mandibular advancement oral appliances to reduce upper airway collapsibility or tongue retaining devices are considered medically necessary in adult patients (those age 18 years and older) who have sleep test results where one of the criteria outlined below have been met.

For intra oral appliances such as oral airway dilators, oral orthotics, oral airway devices or mandibular advancement devices – the following criteria must be met:

- A physician with additional training in sleep disorders must evaluate the patient and order this appliance

AND

- The apneic/hypopneic index (AHI) is greater than or equal to 15 events per hour and up to a maximum of 30 events per hour, including a minimum of 30 events documented per sleep study

OR

- The AHI is greater than or equal to 5 events per hour and less than 15 events per hour, including a minimum of 10 events documented per sleep study

AND

- Documented history of stroke

OR

- Documented hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg)

OR

- Documented ischemic heart disease

OR

- Documented symptoms of impaired cognition, mood disorders, or insomnia

OR

- Excessive daytime sleepiness (documented by either Epworth greater than 10 or MSLT less than 6)

OR

- Greater than 20 episodes of desaturation (i.e., oxygen saturation of less than 85%) during a full night sleep study, or any 1 episode of oxygen desaturation (i.e., oxygen

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<table>
<thead>
<tr>
<th>Equipment</th>
<th>Medical Necessity</th>
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OR  
- Greater than 20 episodes of desaturation (i.e., oxygen saturation of less than 85%) during a full night sleep study, or any 1 episode of oxygen desaturation (i.e., oxygen |
Equipment | Medical Necessity
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| saturation of less than 70%)
OR
| Obesity (BMI greater than 35)
• If the AHI is greater than 30 events per hour and meets either of the following:
| The patient is not able to tolerate a positive airway pressure (PAP) device
OR
| The use of the PAP device is contraindicated

Intraoral appliances for children | Mandibular advancement oral appliances to reduce upper airway collapsibility or tongue retaining devices are considered not medically necessary as they are not recommended for pediatric patients (those under 18 years of age) due to lack of mature bite development.

**Coding**

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
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<tr>
<td>E0485</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment</td>
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<tr>
<td>E0486</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment</td>
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**Related Information**

Obstructive Sleep Apnea (OSA) is defined as:

- **Mild OSA:** AHI greater than 5/hr. and less than 15/hr
- **Moderate OSA:** AHI of 15/hr. or greater and 30/hr. or less
- **Severe OSA:** AHI of greater than 30/hr
A 2013 randomized cross-over trial by Phillips et al. found similar health outcomes after 1 month of CPAP or oral appliance therapy (OAT) in 126 patients (82% with moderate to severe OSA, AHI >15). CPAP was more effective than mandibular advancement therapy in reducing AHI (CPAP AHI=4.5, OAT AHI=11.1), but patient-reported compliance was higher with OAT (6.5 vs. 5.2 hours/night). Neither treatment improved the primary outcome of 24-hour ambulatory blood pressure, except in a subgroup of patients who were initially hypertensive. The 2 treatments resulted in similar improvements in sleepiness (improvement of 1.6 to 1.9), FOSQ (improvement of 1.0), some measures on driving simulator performance, and disease-specific quality of life (QOL). OAT was superior to CPAP in 4 domains on the SF-36.

In 2013, a systematic review and meta-analysis was performed to compare the outcomes of oral appliances (OAs) with those of CPAP in treatment of patients with obstructive sleep apnea (OSA). The conclusions showed CPAP yielded better polysomnography outcomes, especially in reducing AHI, than OAs, indicating that OAs were less effective than CPAP in improving sleep-disordered breathing. However, similar results from OAs and CPAP in terms of clinical and other related outcomes were found, suggesting that it would appear proper to offer OAs to patients who are unable or unwilling to persist with CPAP.

**Pediatric Patients**

In the pediatric population, chronic snoring is abnormal. “Pediatric sleep-disordered breathing is a continuum, with primary snoring at one end, and complete upper airway obstruction, hypoxemia, and obstructive hypoventilation at the other.” Sleep disordered breathing symptoms are often attributed to enlarged tonsils and adenoids, but multiple possible anatomic obstructions need to be properly evaluated. Craniofacial and occlusal disharmony may be a significant underlying factor in the development and progression of pediatric sleep disorders.

Properly assessing facial and dental morphometric associations requires a comprehensive orthodontic evaluation as well as a pediatric [ENT] assessment for potential airway obstructions including enlarged tonsils and adenoids. “In contrast to sleep–disordered breathing or sleep apnea in adults, which is predominantly associated with obesity, sleep-disordered breathing symptoms is in this pediatric cohort primarily associated with adenotonsillar hypertrophy, morphologic features related to a long and narrow face [dolichofacial, height mandibular plane
angle, narrow palate, and severe crowding in the maxilla and the mandible] allergies, frequent colds, and habitual mouth breathing."^8.

A primary concern is that indiscriminate use of a mandibular advancement device (MAD) [E0486] “in a growing child and/or adolescent may result in dramatic skeletal and dentofacial changes”.^9 The limited benefits of a MAD, can be far outweighed by dramatic and unplanned craniofacial skeletal changes in a growing individual. The causes for sleep-disordered breathing symptoms in young adults are so varied that comprehensive medical/orthodontic workup is essential before any course of therapy is warranted.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

The American Academy of Craniofacial Pain (AACP)

The American Academy of Craniofacial Pain (AACP) Task Force on Mandibular Advancement Oral Appliance Therapy for Snoring and Obstructive Sleep Apnea published a position paper in 2013. The position paper states that oral appliance therapy is recognized as an effective therapy for many with primary snoring and mild to moderate OSA, as well as those with more severe OSA who cannot tolerate PAP therapies, but that oral appliance therapy has the potential to cause adverse effects including temporomandibular joint (TMJ) pain and dysfunction. The authors recommend that dentists engaged in, or who wish to engage in, the assessment and management of patients with snoring and OSA using mandibular advancement oral appliances should be properly trained and experienced in the assessment, diagnosis and management of TMJ and craniofacial pain.

National Institute for Health and Clinical Excellence (NICE)

National Institute for Health and Clinical Excellence (NICE) in 2008, issued guidance on CPAP treatment of OSA, based on a review of the literature and expert opinion. The recommendations included:

- CPAP treatments aim to reduce daytime sleepiness by reducing the number of episodes of apnea/hypopnea experienced during sleep. The alternatives to CPAP are lifestyle management, dental devices, and surgery. Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption. Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has
been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS. Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice.

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>07/14/14</td>
<td>New policy. Intraoral appliance information pulled from policy 2.01.503. Policy held for provider notification and will become effective October 23, 2014.</td>
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<tr>
<td>10/23/14</td>
<td>Reissue policy as updates are now effective; reference to previous version removed.</td>
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<tr>
<td>05/27/15</td>
<td>Annual Review. Policy updated with literature review. Definition of OSA added to Policy section; no change in policy statements.</td>
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10/11/16  Annual Review. No change in policy statements. Policy moved to new format.

03/14/17  Annual Review. References 7, 8, and 9 were added. Statement added to clarify non-application to pediatric patients; oral devices are considered not medically necessary as they are not recommended for this patient population. Age of pediatric patient clarified as under age 18.

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Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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Arabic (Arabic):

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