MEDICAL POLICY

MEDICAL POLICY DETAILS

<table>
<thead>
<tr>
<th>Medical Policy Title</th>
<th>ORAL APPLIANCES FOR THE TREATMENT OF SLEEP-RELATED BREATHING DISORDERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number</td>
<td>1.01.07</td>
</tr>
<tr>
<td>Category</td>
<td>Equipment/Supplies</td>
</tr>
<tr>
<td>Effective Date</td>
<td>07/02/99</td>
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<tr>
<td>Revised Date</td>
<td>06/20/01, 03/21/02, 3/20/03, 03/25/04, 04/28/05, 02/23/06, 02/22/07, 02/28/08</td>
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<tr>
<td>Archived Date</td>
<td>02/26/09</td>
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<td>02/25/10, 02/24/11, 02/27/12, 02/28/13, 02/27/14, 02/26/15, 02/25/16, 04/27/17, 02/22/18, 08/22/19</td>
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</table>
| Product Disclaimer                                        | • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.
• If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.
• If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. |

POLICY STATEMENT

I. Based upon our criteria and review of peer-reviewed literature, oral appliances for the treatment of clinically documented mild to moderate obstructive sleep apnea (Respiratory Disturbance Index [RDI] or Apnea/Hypopnea Index [AHI] of greater than 5 and less than 30) have been medically proven to be effective and therefore, medically appropriate.

II. Based upon our criteria and assessment of peer-reviewed literature, oral appliances are considered medically appropriate as a treatment option for severe obstructive sleep apnea (RDI/AHI greater than or equal to 30) when the patient is intolerant of CPAP, is not considered a surgical candidate, or refuses CPAP or surgical intervention.

III. Based upon our criteria and assessment of peer-reviewed literature, oral appliances for the treatment of upper airway resistance syndrome (UARS) with or without snoring and without obstructive sleep apnea (OSA) are considered not medically necessary.

IV. Replacement of a medically necessary oral appliance is eligible for coverage after 2 years unless the patient has experienced a change in his or her physiological condition (e.g., tooth loss or major dental reconstruction).

V. Replacement needed due to misuse or neglect (e.g., lost or misplaced) is ineligible for coverage.

Refer to Corporate Medical Policy #7.01.41 regarding Surgical Management of Sleep Disorders.

Refer to Corporate Medical Policy # 11.01.17 regarding Temporomandibular Joint Disease

POLICY GUIDELINES

I. Attempts at behavioral modifications and life style changes (e.g., good sleep hygiene, weight loss, avoidance of alcohol consumption in evening, smoking cessation, sleep position change, treatment of nasal congestion) for patients with UARS and sleep apnea should be an integral part of the treatment regimen for sleep disordered breathing.

II. The decision for the use and fabrication of an oral appliance should be made by sleep medicine physician (e.g., special specialist, Ear Nose and Throat (ENT) specialist) or by an experienced dentist/orthodontist in collaboration with a sleep specialist.
Medical Policy: ORAL APPLIANCES FOR THE TREATMENT OF SLEEP-RELATED BREATHING DISORDERS
Policy Number: 1.01.07
Page: 2 of 4

III. All impressions, try-ins, and adjustments and repairs are inclusive to the lifetime of the appliance after approval of the device.

DESCRIPTION

Sleep disordered breathing includes a variety of breathing disturbances that occur during sleep, exemplified by snoring, hypoventilation, apnea, increased upper airway resistance and nocturnal asthma. Primary snoring refers to snoring that is not accompanied by apnea, hypoventilation or excessive sleepiness.

Obstructive sleep apnea syndrome (OSAS) results from upper airway obstruction and is defined as the cessation of airflow through the nose and mouth for at least 10 seconds with a respiratory effort noted. OSAS has been shown to cause increased morbidity and mortality from cardiovascular complications including hypertension and cardiac arrhythmias. OSAS is characterized by excessive daytime sleepiness, impaired cognition and mood disorders. Mild to moderate OSA is defined as having an Apnea/Hypopnea Index (AHI), or Respiratory Disturbance Index (RDI), of 5 to 30 episodes per hour of sleep during diagnostic laboratory polysomnography (sleep study). A patient with severe OSA has been found to have a RDI or AHI greater than 30.

Upper Airway Resistance Syndrome (UARS) develops because of a relaxation in the throat, which makes it harder to inhale, and increases the work of breathing. The increased respiratory effort exerted by UARS patients during narrowing of the airway causes pressure swings within the chest. These fluctuations in pressure can be measured with esophageal monitoring during a polysomnogram. UARS is characterized by repetitive EEG arousals from sleep, which leads to sleep deprivation and resultant daytime sleepiness and chronic fatigue.

Oral appliances (OA) that treat snoring, upper airway resistance syndrome (UARS) and Obstructive Sleep Apnea (OSA) are devices placed in the mouth and utilized during sleep to prevent the collapse of the upper airway thus maintaining patency to allow adequate ventilation and prevent sleep apnic episodes. These appliances may be used as an alternative to other medical (e.g., continuous positive airway pressure – CPAP) and surgical (e.g., uvulopalatopharyngoplasty – UPPP) interventions for mild to moderate OSA. The most common types of appliances are the Mandibular Repositioning Device and the Tongue Retaining Device.

RATIONALE

The consistency of the findings among studies support the use of oral appliances as an alternative treatment method for patients with sleep-related breathing disorders. A systematic review by J Lim, et al (2006) concluded the following: There is evidence suggesting that OA improves subjective sleepiness and sleep disordered breathing compared with a control. CPAP appears to be more effective in improving sleep disordered breathing than OA. The difference in symptomatic response between these two treatments is not significant, although it is not possible to exclude an effect in favor of either therapy. Until there is more definitive evidence on the effectiveness of OA in relation to CPAP, with regard to symptoms and long-term complications, it is appropriate to recommend OA therapy to patients with mild symptomatic OSAH, and those patients who are unwilling or unable to tolerate CPAP therapy.

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.
- CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>No specific code(s)</td>
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</tr>
</tbody>
</table>

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# Medical Policy: ORAL APPLIANCES FOR THE TREATMENT OF SLEEP-RELATED BREATHING DISORDERS

**Policy Number:** 1.01.07

**Page:** 3 of 4

## HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0485</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment</td>
</tr>
<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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## ICD10 Codes

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>F51.8</td>
<td>Other sleep disorders not due to a substance or known physiological condition</td>
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<tr>
<td>G47.00-G47.09</td>
<td>Insomnia (code range)</td>
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<tr>
<td>G47.10-G47.19</td>
<td>Hypersomnia (code range)</td>
</tr>
<tr>
<td>G47.20-G47.29</td>
<td>Circadian rhythm sleep disorder (code range)</td>
</tr>
<tr>
<td>G47.30-G47.39</td>
<td>Sleep apnea (code range)</td>
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<tr>
<td>G47.69</td>
<td>Other sleep related movement disorders</td>
</tr>
<tr>
<td>G47.8-G47.9</td>
<td>Other and unspecified sleep disorder (code range)</td>
</tr>
</tbody>
</table>

## REFERENCES


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Medical Policy: ORAL APPLIANCES FOR THE TREATMENT OF SLEEP-RELATED BREATHING DISORDERS
Policy Number: 1.01.07
Page: 4 of 4


*Key Article

KEY WORDS
Obstructive sleep apnea, OSA, Upper Airway Resistance Syndrome

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) addressing Oral Appliances for Obstructive Sleep Apnea. Please refer to the following website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33611&ContrId=389&ver=14&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAgAAAQAAAAA

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