MEDICAL POLICY

SUBJECT: ORAL APPLIANCES FOR THE TREATMENT OF SLEEP-RELATED BREATHING DISORDERS

POLICY NUMBER: 1.01.07
CATEGORY: Equipment/Supplies
EFFECTIVE DATE: 07/02/99
REVISED DATE: 06/20/01, 03/21/02, 3/20/03, 03/25/04, 04/28/05, 02/23/06, 02/22/07, 02/28/08
ARCHIVED DATE: 02/26/09
EDITED DATE: 02/25/10, 02/24/11, 02/27/12, 02/28/13, 02/27/14, 02/26/15, 02/25/16, 04/27/17

• 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, 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 5-30) 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 30) when the patient is intolerant of CPAP, is not considered a surgical candidate, or refuses CPAP or surgical intervention.

III. Based on our criteria and assessment of peer-reviewed literature, oral appliances for the treatment of clinically documented upper airway resistance syndrome (UARS) are considered medically appropriate as treatment option when attempts at behavioral modification have failed.

IV. Based upon our criteria and assessment of peer-reviewed literature, oral appliances for the treatment of primary snoring without evidence of UARS or obstructive sleep apnea (OSA) are considered not medically necessary.

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 an experienced dentist/orthodontist in collaboration with a sleep specialist.

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 apneic 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.

**RATIONALITY:**

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 would appear to be appropriate to recommend OA therapy to patients with mild symptomatic OSAH, and those patients who are unwilling or unable to tolerate CPAP therapy.

**CODES:**

<table>
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<tr>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract. Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.</td>
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<tr>
<td>CPT:</td>
<td>No specific code(s)</td>
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<tr>
<td>HCPCS:</td>
<td>E0485 Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment</td>
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<td>ICD9:</td>
<td>780.50-.59 Sleep disturbances (code range)</td>
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<td>ICD10:</td>
<td>F51.8 Other sleep disorders not due to a substance or known physiological condition</td>
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REFERENCES:

Policy previously titled “Nocturnal Airway Patency Appliance (NAPA)”.


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