MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Oral Appliance for the Treatment of Obstructive Sleep Apnea**
Policy Number	**1.01.07**
Category	**Contract Clarification**
Original Effective Date	**10/18/01**
Committee Approval Date	**10/18/01, 03/21/02, 3/20/03, 03/25/04, 04/28/05, 02/23/06, 02/22/07, 02/28/08**
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Archive Review 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, 02/22/18, 08/22/19, 10/22/20, 10/28/21, 07/21/22, 08/17/23, 08/22/24**
Product Disclaimer	• *Services are contract dependent; 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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the 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, are considered **medically appropriate**.

II. Based upon our criteria and assessment of the peer-reviewed literature, oral appliances have been medically proven to be effective and, therefore, are considered **medically appropriate** as a treatment option for severe obstructive sleep apnea (RDI/AHI greater than or equal to 30), when **ANY** of the following criteria are met:
   1. when the patient is intolerant or refuses CPAP therapy;
   2. is not considered a surgical candidate or refuses surgical intervention.

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

IV. Based upon our criteria and assessment of the peer-reviewed literature, the use of daytime neuromuscular electrical stimulation of the tongue (e.g., eXciteOSA, Signifier Medical Technologies, LLC) has not been medically proven to be effective and, therefore, is considered **investigational** for the treatment of OSA.

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

Refer to Corporate Medical Policy #11.01.17 Temporomandibular Joint Disorder (TMJD)

POLICY GUIDELINES

I. Attempts at behavioral modifications and lifestyle 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 a sleep medicine physician (e.g., somnologist or sleep specialist; ear, nose, and throat [ENT] specialist) or by an experienced dentist/orthodontist in collaboration with a sleep specialist.

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

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

V. Replacement of a medically necessary oral appliance needed due to misuse or neglect (e.g., lost or misplaced) is **ineligible for coverage**.

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 OSAS is defined as having an Apnea/Hypopnea Index (AHI), or Respiratory Disturbance Index (RDI), of five to 30 episodes per hour of sleep during diagnostic laboratory polysomnography (sleep study). A patient with severe OSAS has been found to have an 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 lead 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 OSAS. The most common types of appliances are the Mandibular Repositioning Device and the Tongue-Retaining Device.

The eXciteOSA is a novel daytime treatment for snoring and sleep apnea that delivers neuromuscular electrical stimulation via four electrodes in a hand-held device to stimulate and improve muscle function in the mouth and tongue. The device, used for 20 minutes per day for six weeks, trains your tongue to stay in its natural position during sleep. An app that is downloaded to a smart phone controls the intensity of the stimulation and provider guidance, reminders, and notifications about an individual's therapy.

RATIONALE

The consistent 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) reached the following conclusions: 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 OSAS and to patients who are unwilling or unable to tolerate CPAP therapy.

Two cohort studies (Kotecha et al. (2021) and Baptista et al. (2021)) studied habitual snorers who were treated with eXciteOSA. Both studies reported a reduction in snoring time measured by the Watch-PAT device and bed-partner-reported snorting was also decreased. A reduction in AHI was noted in those participants with mild OSA in the Kotecha study but there was no clinically significant reduction in AHI reported in the Baptista study. Both the Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI) test showed improvements as reported by the participants as well as the bed partners. These studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is uncertain.

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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
No specific code(s)	

HCPCS Codes

Code	Description
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment
E0490 **(E/I)**	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote *(Effective 10/01/23)*
E0491 **(E/I)**	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
E0492 **(E/I)** K1028 **(E/I)** Termed 12/31/23	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application *(Effective 01/01/24) (Replacing code K1028)* Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application

Code	Description
E0493 **(E/I)**	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply *(Effective 01/01/24)* (*Replacing K1029)*
K1029 Termed 12/31/23	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
K1037	Docking station for use with oral device/appliance used to reduce upper airway collapsibility *(Effective 04/01/24)*

ICD10 Codes

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

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*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 (L33611). Please refer to the following website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33611] accessed 07/15/24.