

NON-SURGICAL TREATMENT OF OBSTRUCTIVE SLEEP APNEA

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Related Medical Policies:

- Polysomnography and Portable Monitoring for Evaluation of Sleep Related Breathing Disorders
- Surgical Treatment of Obstructive Sleep Apnea

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Related Coverage Determination Guidelines:
None

INSTRUCTIONS FOR USE

This Medical policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this medical policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

COVERAGE RATIONALE

Removable oral appliances are proven for treating mild or moderate obstructive sleep apnea (OSA) as documented by polysomnography. Refer to the Medical Policy titled Polysomnography and Portable Monitoring for Evaluation of Sleep Related Breathing Disorders for further information.

Staging of the severity of sleep apnea can be accomplished by using the apnea-hypopnea index (AHI), also called the respiratory disturbance index (RDI). The American Academy of Sleep Medicine (AASM) defines OSA as follows:

- Mild OSA - AHI of 5-15
- Moderate OSA - AHI of 15-30
- Severe OSA - AHI of greater than 30

Removable oral appliances are unproven for treating central sleep apnea.

This type of sleep apnea is caused by impaired neurological function, and these devices are designed to manage physical obstructions.

BACKGROUND

Obstructive sleep apnea (OSA) is a breathing disorder that is defined by either a decrease or complete cessation of airflow during sleep. In OSA, airflow is obstructed when the muscles in the back of the throat fail to keep the airway open. Nocturnal respiration in patients with OSA is characterized by apnea (breathing cessation) and hypopnea (marked reduction in breathing volume). The signs and symptoms of untreated OSA include excessive daytime sleepiness, loud snoring, nocturnal choking, apneas or choking witnessed by bed partner, unrefreshing sleep, morning headaches, reduced libido and enuresis. Physiological effects of untreated OSA include fluctuating blood oxygen levels, increased heart rate, chronic daytime hypertension and impaired glucose tolerance/insulin resistance.

Diagnosis and evaluation of sleep apnea syndrome is determined through polysomnography (PSG). Staging of the severity of sleep apnea can be accomplished by using the apnea-hypopnea index (AHI), also called the respiratory disturbance index (RDI). The American Academy of Sleep Medicine (AASM) defines mild OSA as an AHI of 5-15, moderate OSA as an AHI of 15-30 and severe OSA as an AHI of greater than 30 (AASM, 2008).

Treatment for OSA includes lifestyle modifications (weight loss, avoidance of alcohol or other agents that decrease upper airway patency), positional therapy, positive airway pressure (CPAP or BiPAP), oral appliance therapy and surgery.

Non-surgical oral appliances, worn during sleep, are intended to treat OSA by keeping the airway open in one of three ways: by pushing the lower jaw forward (a mandibular advancement device or MAD), by preventing the tongue from falling back over the airway (a tongue-retaining device) or by combining both mechanisms (ASAA, 2007).

CLINICAL EVIDENCE

There is sufficient evidence to conclude that mandibular advancement devices (MAD) can improve sleep-disordered breathing in patients with mild to moderate OSA who prefer it to CPAP, do not respond to CPAP or fail treatment with CPAP. MAD therapy is more effective than placebo therapy but less effective than CPAP therapy for reducing sleep-disordered breathing (Hayes, 2010).

In a multicenter, randomized controlled trial (n=101), Lam et al. (2007) compared the effectiveness of three commonly used non-surgical treatment modalities in patients with mild to moderate OSA. Treatment groups consisted of conservative measures (sleep hygiene) only, continuous positive airways pressure (CPAP) in addition to conservative measures or an oral appliance in addition to conservative measures. The severity of sleep-disordered breathing was decreased in the CPAP and oral appliance groups compared with the conservative measures group, and the CPAP group was significantly better than the oral appliance group. Overall, CPAP produced the best improvement in terms of physiological, symptomatic and quality of life measures, while the oral appliance was slightly less effective.

A Cochrane review concluded that while CPAP appears to be more effective in improving sleep disordered breathing, there is increasing evidence suggesting that oral appliances (OA) improve subjective sleepiness and sleep disordered breathing compared with a control. 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 OSA, and those patients who are unwilling or unable to tolerate CPAP

therapy. OA should not be considered as first choice therapy for OSA where symptoms and sleep disruption are severe (Lim, 2006; updated 2008).

Ferguson et al. (2006) conducted an evidence-based systematic review regarding the use of oral appliances for treating OSA and concluded that overall, patients with mild to severe OSA have a 52% chance of being able to control their sleep apnea using an appliance. Success rates ranged between 14 and 61% among patients with severe OSA (AHI defined as greater than 30 in some studies and greater than 40 in others). Better success rates were seen in patients with lower AHI. OAs are on the whole less effective than CPAP but may be better accepted by patients than nasal CPAP in studies where subjects used both treatments. OAs are not recommended as a first line treatment in patients with severe OSA. However, these patients might consider an OA if they have failed CPAP or upper airway surgery, recognizing that the results of OA therapy in severe OSA are unpredictable. The literature now provides better evidence for the efficacy of OAs and indications for use.

Tegelberg et al. (2003) compared two different degrees of mandibular advancement with an intraoral appliance in 74 male patients with mild to moderate OSA. Thirty-eight patients received a dental appliance with 50% advancement and 36 patients received a dental appliance with 75% mandibular advancement. Somnography was performed pre-treatment and after one year of treatment. Fifty-five patients completed followup after one year of treatment. In the group of 50% advancement, normalization (an apnea index of <5 and apnea/hypopnea index <10) was observed in 79% of the group. In the group of 75% advancement, normalization was observed in 73% of the group. Less than 5% of the patients reported symptoms from the stomatognathic system; one-third of the patients reported headaches more than once a week. Headaches significantly decreased after one year of treatment.

Thirty-five patients diagnosed with OSA unable to tolerate or non-compliant with CPAP were studied by Prathibha et al. (2003). These patients underwent sleep studies, used intraoral appliances for three months and had a repeat sleep study performed while using the appliance. Thirty-one patients completed the study. Patients with a pre-study AHI <20 benefited from the appliance, while the authors concluded that those patients with a pre-study AHI >20 did not.

Walker-Engstrom et al. (2002) randomized 95 patients with confirmed OSA to treatment with a dental appliance or uvulopalatopharyngoplasty. Patients underwent sleep studies before treatment and 1 year and 4 years after treatment. Thirty-two patients in the dental appliance group and 40 patients in the UPPP group completed the 4-year follow up. Success was defined as a reduction in the apnea index of at least 50%. The dental appliance group had a success rate of 81%; the UPPP group had a success rate of 53%. An apnea index of <5 or an apnea/hypopnea index <10 was observed in 63% of the dental-appliance group and 33% of the UPPP group. The compliance rate of the dental appliance group was 62%. Seventy-five percent of the UPPP group were satisfied with their results and required no further complementary treatment.

Professional Societies

American Academy of Sleep Medicine

- Although not as efficacious as continuous positive airway pressure (CPAP), oral appliances are indicated for use in patients with mild to moderate OSA who prefer OAs to CPAP, do not respond to CPAP, are not appropriate candidates for CPAP, fail treatment attempts with CPAP or fail treatment with behavioral measures such as weight loss or sleep position change.
- Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Until there is higher quality evidence to suggest efficacy, CPAP is indicated whenever possible for patients with severe OSA before consideration of oral appliances (Kushida, 2006; Epstein, 2009).

American Sleep Apnea Association

Oral appliances, sometimes called dental appliances, are intended to treat apnea by keeping the airway open in one of three ways: by pushing the lower jaw forward (a mandibular advancement device or MAD), by preventing the tongue from falling back over the airway (a tongue-retaining device) or by combining both mechanisms. Oral appliances are typically more effective for people with mild sleep apnea and for non-obese people but can, for some, be effective for moderate and severe sleep apnea. The most common type of oral appliance, a MAD is often adjustable so that the dentist can move the jaw further or reduce the advancement as necessary. The goal is to find the most comfortable and effective position for the patient. On occasion oral appliances may worsen the apnea (ASAA, 2007).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Oral appliances for OSA are regulated by the FDA, but products are too numerous to list. See the following web site for more information (use product codes LRK or LQZ). Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. Accessed August 25, 2010.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for oral appliances for the treatment of obstructive sleep apnea (OSA). Oral maxillofacial prosthesis used in the treatment of OSA is addressed in the Local Coverage Determinations (LCDs) for Oral Maxillofacial Prosthesis and Treatment of Obstructive Sleep Apnea and compliance with these LCDs is required where applicable. These LCDs are available at http://www.cms.hhs.gov/mcd/index_local_alpha.asp?from=alphalmp&letter=O and http://www.cms.gov/mcd/index_local_alpha.asp?from=alphalmp&letter=T

DME MAC Local Coverage Determinations (LCDs) and Articles for Oral Appliances for Obstructive Sleep Apnea are available; however, these policies are still in DRAFT format. The draft LCDs are available at: http://www.cms.hhs.gov/mcd/index_local_alpha.asp?from=alphalmp&letter=O and the draft articles are available at: http://www.cms.hhs.gov/mcd/index_local_alpha.asp?from=alphaarticle&letter=O.

(Accessed August 12, 2010)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

HCPCS 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
S8262	Mandibular orthopedic repositioning device, each

ICD-9 Code	Description
Proven Diagnosis Codes	
327.20	Organic sleep apnea, unspecified
327.23	Obstructive sleep apnea (adult) (pediatric)
327.29	Other organic sleep apnea
780.51	Insomnia with sleep apnea, unspecified
780.53	Hypersomnia with sleep apnea, unspecified
780.57	Unspecified sleep apnea

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/23/2010	<ul style="list-style-type: none">• No changes to coverage rationale• Removed 327.21 and 327.27 from list of applicable ICD-9 diagnosis codes• Archived previous policy version 2010T0526A