
Medical Policy



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Title: Medical Management of Obstructive Sleep Apnea Syndrome (Oral Appliances and Novel Therapies)

Description/Background

OBSTRUCTIVE SLEEP APNEA

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This causes a drop in blood oxygenation and a brief arousal, and can occur as frequently as every minute throughout the night. The main risk factors for OSA include obesity, male sex, older age, large neck size, instability of the respiratory control system, and craniofacial dysmorphisms; additional factors include cardiovascular disease, diabetes, and metabolic syndrome. Since disorders linked to OSA are more common in ethnic minority groups, there are data supporting an increased risk of OSA in African Americans and American Indians.

The most common signs and symptoms in adults are snoring, excessive daytime sleepiness, and hypertension. Excessive daytime sleepiness may be subjective, and is assessed by questionnaires such as the Epworth Sleepiness Scale, a short self-administered questionnaire that asks individuals how likely they are to fall asleep in different scenarios such as watching TV, sitting quietly in a car, or sitting and talking to someone. Daytime sleepiness is uncommon in young children with OSA. Symptoms in children may include disturbed sleep and daytime neurobehavioral problems. In otherwise healthy children, OSA is usually associated with adenotonsillar hypertrophy and/or obesity.

The hallmark of OSA is snoring. During apneic episodes and the brief period of arousal that follows, an individual's snoring abruptly ceases and then resumes when the individual falls asleep again. The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adults with OSA-associated daytime somnolence are thought to be at higher risk for collisions involving motorized vehicles, i.e., cars, trucks, or heavy equipment, while OSA in children may result in neurocognitive impairment and behavioral problems.

Cardiovascular and pulmonary systems can also be affected by OSA.¹ For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor pulmonale. Systemic hypertension is common in individuals with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile collisions related to daytime sleepiness. It is estimated that about 7% of adults have moderate or severe OSA, and 20% have at least mild OSA, and individuals referred for evaluation of OSA represent only a small proportion of those who have clinically significant and treatable disease.¹

Diagnosis

Obstructive sleep apnea is widely underdiagnosed with up to 95% of individuals with clinically significant OSA reporting no prior OSA diagnosis. Moreover, underdiagnosis is particularly prevalent in Black individuals. The criterion standard diagnostic test for sleep disorders is a polysomnogram performed in a sleep laboratory.² A standard polysomnogram includes EEG, submental electromyogram (EMG) and electrooculogram (to detect rapid eye movement [REM] sleep) for sleep staging. Polysomnography (PSG) also typically includes electrocardiography and monitoring of respiratory airflow and effort, snoring, oxygen desaturation, and sleep position. An attended study ensures that the electrodes and sensors are functioning adequately and do not dislodge during the night. In addition, an attendant is able to identify severe OSA in the first part of the night and titrate continuous positive airway pressure (CPAP) in the second part of the night, commonly known as a "split-night" study. If successful, this strategy eliminates the need for an additional PSG for CPAP titration.

Table 1. Definitions of Terms and Scoring Criteria for OSA

Terms	Definition
Respiratory event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 3 or 4% decrease in arterial oxygen desaturation (depending on the scoring criteria) or an arousal. Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or associated arousal.
RERA	Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea
Respiratory event reporting	
AHI	The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available.
OSA	Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
Mild OSA	In adults: AHI or RDI of 5 to <15. In children: AHI $\geq$ 1 to <5

Moderate OSA	AHI or RDI of 15 to < 30; Children: AHI of ≥ 5 to <10
Severe OSA	Adults: AHI or RDI ≥ 30 ; Children: AHI of ≥ 10
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.
Positive airway pressure	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP
PAP	Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure.
PAP failure	Usually defined as an AHI >20 events per hour while using CPAP
PAP intolerance	CPAP use for <4 hours per night for ≥ 5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in individuals with mild, moderate, or severe OSA

AHI: Apnea/hypopnea Index; APAP: auto-adjusting positive airway pressure; EEG: electroencephalogram; OSA: obstructive sleep apnea; PAP: positive airway pressure; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal; UARS: upper airway resistance syndrome.

Treatment

Conventional medical management of OSA in adults includes weight loss, avoidance of stimulants, body position adjustment, oral appliances and the use of various types of positive airway pressure (i.e., fixed CPAP, bilevel positive airway pressure, or auto-adjusting positive airway pressure) during sleep. There is no established threshold for significant change in weight. Studies have reported improvements in OSA with an average weight loss of 20 kg or 20% of body weight.

This evidence review addresses oral appliances and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (mRNA) (BioModeling Solutions), eXciteOSA, Provent, ULTeapap™ and Winx. The Daytime-Nighttime Appliance (DNA Appliance) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance) are customized palate and mandible expanding devices. eXciteOSA (Signifier Medical Technologies) uses daytime stimulation of the tongue to increase muscle tone with the goal of reducing snoring and mild sleep apnea. Provent is a nasal expiratory positive airway pressure (EPAP) device that uses a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. ULTeapap™ is a nasal expiratory positive airway pressure (EPAP) device that consists of headgear and nasal pillows in small, medium, and large sizes which contain valves that collapse when the individual inhales and inflate when the individual exhales. It does not require a blower, filter, hose, humidifier, or power source. The Winx system uses oral pressure therapy to treat OSA.

Positional Obstructive Sleep Apnea and Therapy

Body position during sleep influences the frequency of apneas and hypopneas in 50-60% of those with OSA. In these cases, AHI is increased when the person is in the supine position, and the AHI decreases in the lateral (side-lying) position.³ There are many devices that propose “positional therapy” or “sleep positional training” for OSA. These devices may include home-made or retail items such as a vest with a pouch on the back to hold tennis balls, or a t-shirt with a center back pocket, also to house a tennis ball. These devices discourage supine sleeping. The U.S. Food and Drug Administration approved the NightBalance Lunoa SPT, a

device which straps to the chest and emits a vibration to encourage movement from a supine position to a side-lying position.

Surgical management of OSA (i.e., adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in the policy titled “Obstructive Sleep Apnea and Snoring – Surgical Treatment”.

Positive airway pressure for the management of OSA is discussed in the policy titled “Positive Pressure Airway Devices”.

Treatment of individuals diagnosed with OSA should be initiated and monitored by a physician who is board-certified in sleep medicine. It is important to monitor symptoms and adherence to positive airway pressure (PAP) treatment (e.g., review of symptoms and device utilization at 90 days with a minimum of 4 hours per night for at least 5 nights per week).

Risk Factors for OSA

Although not an exclusive list, individuals with all 4 of the following symptoms are considered to be at high risk for obstructive sleep apnea (OSA):

- habitual snoring;
- observed apneas;
- excessive daytime sleepiness;
- a body mass index (BMI) greater than 35 kg/m².

If no bed partner is available to report snoring or observed apneas, other signs and symptoms suggestive of OSA (e.g., age of the individual, male gender, thick neck, craniofacial or upper airway soft tissue abnormalities, or unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; however, at present, risk assessment is based primarily on clinical judgment.

The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender) and has been shown to have 97% sensitivity and 96% negative predictive value (specificity, 33%) for the identification of individuals with severe OSA (Apnea/Hypopnea Index [AHI] score >30 events per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is not adequate for the diagnosis of OSA. Therefore, a follow-up polysomnography (PSG) or home sleep study/home sleep apnea test would still be required to confirm or exclude a diagnosis of OSA.

OSA in Children

The presentation of OSA in children may differ from that of adults. In addition, the first-line treatment in children is usually adenotonsillectomy. Continuous positive airway pressure (CPAP) is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

Regulatory Status:

A variety of oral appliances have been cleared for marketing clearance by U.S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of snoring and mild-to-moderate OSA, including the Narval CC™, Lamberg SleepWell Smarttrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, DeSRA, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device. FDA product code: LQZ.

Various PAP devices have been cleared by the FDA through the 510(k) process since 1977. Bilevel PAP devices were first cleared for marketing in 1996. FDA product codes: BZD, MNT.

Novel devices for OSA diagnosis and treatment are described in Table 2.

Table 2. Novel Devices for OSA Diagnosis and Treatment

Device	Manufacturer	Description	FDA Marketing Clearance	FDA Product Code	Year
Diagnosis					
SleepImage System	MyCardio	Software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor to aid in the evaluation of sleep disorders.	K163696	MNR	2017
Treatment					
Provent®	Ventus Medical	Nasal expiratory resistance valve.		OHP	2010
ULTEPAP™	BRYGGS Medical, LLC	Nasal expiratory resistance valve.	K191728	OHP	2020
Winx™		Oral pressure therapy.		OZR	2012
mRNA Appliance®	BioModeling Solutions	Expandable oral appliance for the treatment of snoring and mild-to-moderate OSA	K130067	LRK	2014
NightBalance Lunoa System	Philips	The positional sleep trainer is worn with an elasticized chest strap, and is intended to keep individuals with positional obstructive sleep apnea from sleeping in the supine position.	K180608	MYB	2018
eXciteOSA®	Signifier Medical Technologies	The device delivers neuromuscular stimulation during the day to strengthen the tongue in order to reduce snoring and mild sleep apnea. It is used for 20 minutes once a day for a period of 6-weeks, and once a week thereafter.	DEN200018	QNO	2021

FDA: Food and Drug Administration; OSA: obstructive sleep apnea

Medical Policy Statement

The safety and effectiveness of oral appliances to reduce upper airway collapsibility in the treatment of OSA have been established. An oral appliance may be considered a useful therapeutic option when indicated.

Palate and mandible expansion devices are considered **experimental/investigational** for the treatment of OSA. There is insufficient evidence in the current medical literature to support their efficacy and use in clinical practice.

Nasal Expiratory Positive Airway Pressure (nasal EPAP), used for the treatment of OSA is considered **experimental/investigational**. There is insufficient evidence in the current medical literature to support its efficacy and use in clinical practice.

Oral pressure therapy for the treatment of OSA is considered **experimental/investigational**. There is insufficient medical literature found to support its efficacy.

The use of sleep positioning trainers with vibration, such as the NightBalance Lunoa SPT system, for the treatment of positional OSA are considered **experimental/investigational**. They have not been proven to be more effective than standard care.

The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered **experimental/investigational**.

The use of daytime electrical stimulation of the tongue is considered **experimental/investigational** for the treatment of OSA.

Inclusionary and Exclusionary Guidelines

INCLUSIONS FOR INTRAORAL APPLIANCES (TONGUE-RETAINING DEVICES OR MANDIBULAR ADVANCING/POSITIONING DEVICES:

- Diagnosis of OSA, as defined by:
 - an AHI, RDI or REI of at least 15 events per hour, OR
 - an AHI, RDI or REI of at least 5 events per hour in an individual with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke), AND
- A trial of CPAP has failed, is not tolerated by the individual, or is contraindicated; AND
- The device is prescribed by the treating physician; AND
- The device is custom-fitted by a dentist (preferably a dentist with certification/additional training in dental sleep medicine); AND
- There is a dental evaluation that documents:
 - absence of both temporomandibular dysfunction and periodontal disease.

Impressions, models, fabrication, materials, insertion/fitting, training, subsequent adjustments/modifications of the appliance, repairs and ancillary appliances are included with the OSA appliance and are not separately billable for the first 90 days after provision of the oral appliance.

Replacement of an oral appliance may be considered at the end of the 5-year reasonable useful lifetime (RUL), or prior, if there is a change in the individual's condition.

ORAL APPLIANCES for OSA (e.g., tongue-retaining devices or mandibular orthopedic positioning devices), may be considered established in adult individuals with clinically significant OSA. (Verify coverage of intraoral appliances under the DME benefit.)

Definition of an Oral Appliance for OSA³⁵

- A custom-fabricated appliance, using digital or physical impressions and models of an individual individual's oral structures and physical needs
- NOT a prefabricated item that is modified. Prefabricated components may be included in the final appliance.
- Includes all appliances, including titration appliances
- Made of biocompatible materials
- Engages the maxillary and mandibular arches
- Includes a mechanism that advances the mandible in increments of 1 mm or less with a protrusive adjustment range of at least 5 mm. This mechanism may or may not include fixed mechanical hinges or metallic materials.
- Reversal of the advancement is possible
- The protrusive setting must be verifiable³⁵

An appropriate oral appliance will allow for optimal protrusion of the mandible (e.g., less than 5 mm) to produce the desired relative opening of the airway, without contributing to an increased risk of temporal mandibular joint dysfunction.

PAP THERAPIES i.e., continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP), bilevel positive airway pressure (BiPAP) and variable positive airway pressure (VPAP) may be considered medically necessary for the management of OSA, central sleep apnea or mixed apnea. These devices for treatment are addressed in policy titled "Positive Pressure Airway Devices".

EXCLUSIONS:

- The use of intraoral appliances that do not meet the above criteria are considered **experimental/investigational** for the treatment of OSA.
- Prefabricated (not custom-fit) devices (e.g., sport mouth guards, mouth guards which can be purchased in a retail store or pharmacy)
- Screening tests (e.g., questionnaire, pulse oximetry, rhinometry, and laryngometry, etc.) performed by a dentist

The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered **experimental/investigational**.

The use of daytime electrical stimulation of the tongue is considered **experimental/investigational** for the treatment of OSA.

Palate and mandible expansion devices for the treatment of OSA are considered **experimental/investigational**.

Nasal Expiratory Positive Airway Pressure and oral pressure therapy devices are considered **experimental/investigational**.

The use of sleep positioning trainers with vibration, such as the NightBalance Lunoa SPT system, for the treatment of positional OSA are considered **experimental/investigational**.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

E0486

Other codes (investigational, not medically necessary, etc.):

A7047	A7049	E0485	E1399	K1001
K1028	K1029			

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

DIAGNOSED OBSTRUCTIVE SLEEP APNEA

Clinical Context and Therapy Purpose

The purpose of medical management in individuals who have obstructive sleep apnea (OSA) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does management oral appliances, or novel OSA treatments improve the net health outcome in individuals who have OSA?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with OSA.

Interventions

Positive airway pressure therapies for the treatment of OSA are addressed in the policy titled “Positive Pressure Airway Devices”.

Oral appliances can be broadly categorized as mandibular advancing or positioning devices or tongue retaining devices. Oral appliances can either be “off the shelf” or customized for the individual by a dental laboratory or similar provider.

The Daytime-Nighttime Appliance (DNA Appliance) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance) are customized palate and mandible expanding devices. In addition to the upper-jaw device that is common to both the DNA Appliance and the mRNA Appliance (worn both during the day and night), the mRNA Appliance moves the mandible forward and is worn during sleep. The DNA Appliance and mRNA Appliance systems use 3-dimensional axial springs, which are proposed to expand the upper and lower jaw and airway gradually to treat and eventually eliminate mild-to-moderate OSA.

eXciteOSA (Signifier Medical Technologies) uses daytime stimulation of the tongue to increase muscle tone with the goal of reducing snoring and mild sleep apnea.

NightBalance Sleep Positioning Trainer (Phillips) provides vibration whenever an individual with positional OSA is supine in order to trigger a change in body position.

Other devices being marketed for the treatment of OSA are Provent, ULTepap™ and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. ULTepap™ is a nasal expiratory positive airway pressure (EPAP) device that consists of headgear and nasal pillows in small, medium, and large sizes which contain valves that collapse when the individual inhales and inflate when the individual exhales. It does not require a blower, filter, hose, humidifier, or power source. The Winx system uses oral pressure therapy to treat OSA. Oral pressure therapy provides light negative pressure to the oral cavity by using a flexible mouthpiece connected to a bedside console that delivers negative pressure. This device is proposed to increase the size of the retropalatal airway by pulling the soft palate forward and stabilizing the base of the tongue.

Comparators

The following therapy is currently being used to make decisions about the treatment of OSA. The criterion standard treatment is CPAP or its variants. The major limitation of CPAP is poor individual compliance due to the need to wear a face or nasal mask.

Outcomes

The general outcomes of interest are the number of apneas or hypopneas during sleep, measured by the Apnea/Hypopnea Index (AHI), and subjective symptoms of sleepiness, typically measured with the Epworth Sleepiness Scale (ESS) or the Functional Outcomes of Sleep Questionnaire (FOSQ). Additional health outcome measures relevant to OSA are summarized in Table 3.

Table 3. Health Outcome Measures Relevant to OSA

Outcome	Measure	Description	Clinically Meaningful Difference (If Known)
Change in AHI	AHI	Mean change in AHI from baseline to posttreatment	Change from severe-to-moderate or mild OSA
AHI success	Percentage of individuals achieving success	Studies may use different definitions of success, but the most common for AHI success is the Sher criteria	Sher criteria include a decrease in AHI of $\geq 50\%$ and an AHI < 20 events per hour. Alternative measures of success may be AHI < 15 , < 10 , or < 5 events per hour
ODI	Oxygen levels in blood during sleep	The number of times per hour of sleep that the blood oxygen level drops by ≥ 4 percentage points	More than 5 events per hour
ESS	Scale ranges from 0 to 24	The ESS is a short self-administered questionnaire that asks individuals how likely they are to fall asleep in 8 different situations (e.g., watching TV, sitting quietly in a car, or sitting and talking to someone)	An ESS of ≥ 10 is considered excessively sleepy
FOSQ	30 questions	Disease-specific quality of life questionnaire that evaluates functional status related to excessive sleepiness	A score of ≥ 18 is the threshold for normal sleep-related functioning, and a change of ≥ 2 points is considered a clinically meaningful improvement

AHI: apnea/hypopnea Index; ESS: Epworth Sleepiness

Score; FOSQ: Functional Outcomes of Sleep Questionnaire; MID: minimal important difference; ODI: oxygen desaturation Index; OSA: obstructive sleep apnea; QOL: quality of life.

Beneficial outcomes of a true-positive are effective treatment resulting in a decrease in respiratory events during sleep and a reduction in subject sleepiness.

Harmful outcomes of a false-positive test include unnecessary treatment. Harmful outcomes of a false-negative test include not receiving the correct treatment.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Oral Appliances

Systematic Reviews

In the AHRQ report (2011) on the diagnosis and treatment of OSA in adults, the strength of the evidence that mandibular advancement devices (MADs) improve sleep apnea signs and symptoms was rated moderate.³ More recently, 2 systematic reviews with meta-analysis have compared CPAP with oral devices for the management of OSA.^{4, 5} Pattipati et al (2022) identified literature comparing CPAP with MADs in mild to severe OSA.⁴ A total of 8 RCTs were included in the meta-analysis with a duration of treatment ranging from 4 to 520 weeks. Results demonstrated that CPAP was superior to MADs for reducing post-treatment AHI and lowest post-treatment oxygen desaturation. However, there was no statistically significant difference in the mean post-treatment ESS scores between CPAP and MADs groups.

Another systematic review of the evidence on the treatment of OSA with oral appliance therapy was performed by Ramar et al (2015), as part of an update of practice guidelines by American Academy of Sleep Medicine and the American Academy of Dental Sleep Medicine.⁵ The meta-analysis showed that oral appliances reduced the AHI, arousal index, and Oxygen Desaturation Index, and increased oxygen saturation. However, oral appliances had no significant effect on sleep architecture or sleep efficiency. Furthermore, the meta-analysis found CPAP to be more effective than oral appliances in reducing the AHI, arousal index, and Oxygen Desaturation Index, and in improving oxygen desaturation, supporting the use of CPAP as a first-line therapy for treating OSA. The baseline demographics in regards to racial and ethnic diversity were not reported in either review.

Ready-made Versus Custom-made Mandibular Advancement Devices

Randomized Controlled Trials

Johal et al (2017) reported on a randomized crossover trial of ready-made vs custom-made mandibular repositioning devices.⁶ Twenty-five individuals with mild-to-moderate OSA (mean AHI, 13.3 events per hour; range, 10.9-25 events per hour) were randomized to a 3-month trial of a ready-made or the custom-made device, with a 2-week washout between treatments. An overnight home sleep study was performed at baseline and on the last night of the 3-month trial period. Individuals used the custom-made device for more nights per week (7 vs 3, $p=0.004$) and hours per night (5 vs 3, $p=0.006$) than the ready-made device. Treatment response (AHI <5 events per hour) was obtained in 64% of individuals during use of the custom-made device phase compared with a 24% response rate using the ready-made device ($p<0.001$). Treatment failure (<50% reduction in SHA) was more frequent with the ready-made device (36%) than with the custom device (4%), while an ESS score of at least 10 was more frequent during the ready-made phase (66%) than with the custom-made phase (33%). An improvement in the QOL score was observed only during the custom-made device phase.

Subsection Summary: Oral Appliances

Custom oral appliances, which may include mandibular repositioning or tongue-retaining devices, are an accepted therapy for mild-to-moderate OSA. A 2015 meta-analysis found

efficacy of oral appliances for measures of OSA, but they were less effective than CPAP. The strength of evidence for mandibular repositioning devices was rated as moderate by AHRQ.

Positional Therapy

Van Maanen et al (2013) reported on a study performed in The Netherlands of 36 individuals with mild-to-moderate positional obstructive apnea who were presented with a novel device, the Sleep Position Trainer, for treatment.⁷ Thirty-one individuals completed the one-month trial. The authors concluded that the Sleep Position Trainer was highly successful, well-tolerated and improved sleep-related quality of life.

Eijsvogel et al (2015) reported on compliance of positional therapy in positional obstructive sleep apnea syndrome.⁸ Twenty-nine individuals were treated with the sleep position trainer (SPT) while 26 individuals were treated with the tennis ball technique. At baseline and 1 month polysomnography, the ESS and the Quebec Sleep Questionnaire (QSQ) were taken. Daily compliance was objectively measured in both groups. Both therapies prevent supine sleep position to a median of 0%, resulting in a treatment success (AHI < 5) in 68.0% of the SPT and 42.9% of the TBT individuals. The ESS at baseline was < 10 in both groups. Sleep quality parameters, such as wake after sleep onset and awakenings improved more in the SPT group. The authors concluded that in mild positional obstructive sleep apnea with normal EES, the new SPT device and the standard TBT are equally effective in reducing respiratory indices.

de Ruiter et al (2017)⁹ reported on a study comparing the effectiveness of positional therapy (PT) with the sleep position trainer to oral appliance therapy in individuals with mild-to-moderate positional obstructive sleep apnea. This was a multicenter, prospective, randomized, controlled trial. Individuals with mild-to-moderate POSA (apnea-hypopnea index (AHI) $\geq 5 \leq 30$ /hour sleep) were randomized for PT or oral appliance therapy. Polysomnography was repeated after 3 months. Efficacy, adherence, mean disease alleviation (MDA), quality of life, dropouts and adverse events were evaluated. A total of 177 individuals were screened for the study; 99 underwent randomization and 81 completed the study. Intention-to-treat (ITT) analysis of median [IQR] AHI showed a reduction in the PT group from 13.0 [9.7-18.5] to 7.0 [3.8-12.8], $p < 0.001$ and in the OAT group from 11.7 [9.0-16.2] to 9.1 [4.9-11.7], $p < 0.001$. Mean adherence (≥ 4 h/night, ≥ 5 days/week) was $89.3 \pm 22.4\%$ for SPT versus $81.3 \pm 30.0\%$ in OAT individuals, $p = 0.208$. The authors concluded that oral appliance therapy and positional therapy were equally effective in reducing the median AHI in individuals with mild-to-moderate POSA.

Subsection Summary: Positional Therapy

For those whose body position during sleep influences the frequency of apneas and hypopneas, positional devices that discourage the supine position are effective. However, the devices are not significantly more effective than a tennis ball on the back of a shirt, or oral appliance therapy.

NOVEL OBSTRUCTIVE SLEEP APNEA TREATMENTS

Palate and Mandible Expansion

Singh et al (2016) reported on a series of 15 consecutive individuals with severe sleep apnea who were treated with a DNA Appliance or mRNA Appliance.¹⁰ All individuals had failed to comply with CPAP. Pre- and post-treatment AHI was assessed in a home sleep apnea test without the oral appliance. AHI decreased from a mean 45.9 events per hour to 16.5 ($p < 0.01$) after a mean 9.7 months of treatment. Singh et al (2016) and Cress (2017) reported on a series of 19 individuals who had mild-to-moderate OSA who were treated with a DNA or mRNA Appliance.¹⁷ Only individuals who complied with oral appliance wear were included in the study. The mean AHI was reduced from 12.85 to 6.2 events per hour ($p < 0.001$) with the appliance, while the Oxygen Saturation Index improved from 6.3% to 2.6% ($p < 0.001$). Limitations of these studies included the use of a home sleep apnea test rather than the more accurate laboratory PSG, uncertain blinding of the physician evaluating the sleep study, the small number of individuals studied, the lack of intention-to-treat analysis, and the lack of long-term follow-up.

Subsection Summary: Palate and Mandible Expansion

The evidence on palate and mandible expansion devices includes a few small cohort studies. Further study with well-designed trials is needed to evaluate this treatment.

Daytime Sleep study (PAP-NAP)

The PAP-NAP uses a desensitization program to facilitate adaptation to pressurized air and test advanced PAP modes for intolerance to PAP.

Krakow et al (2008) reported on use of a daytime abbreviated sleep study to acclimate individuals with complex insomnia to PAP.¹¹ Individuals had been referred by psychiatrists or primary care physicians for unspecified insomnia conditions, insomnia due to a mental disorder, or hypnotic dependence. Nearly all individuals had anxiety, fear, and/or resistance regarding PAP therapy or the diagnosis of OSA. Thirty-nine individuals who would not complete a titration protocol (full-night or split-night) were offered a daytime procedure (PAP-NAP) prior to night-time titration. The PAP-NAP protocol had 5 components: pretest instructions to maximize chances for daytime napping; introduction of PAP therapy addressing barriers to use; type 3 monitoring hookup (10 channels without electroencephalography leads); PAP therapy during one to two hours in bed in which the individual had the opportunity to fall asleep with the mask in place; and post-test follow-up. Thirty-five of 39 nap-tested individuals subsequently scheduled and completed an overnight titration or split-night study with full PSG. The effect of the PAP-NAP intervention on compliance was compared with historical controls ($n=38$) who had insomnia, mental health conditions, and OSA with resistance to CPAP who completed titration. A prescription for PAP therapy was filled by 85% of the PAPNAP group compared with 35% of controls. Regular use during a 30-day period was recorded by the PAP device in 67% of the intervention group and in 23% of controls. Adherence, defined as at least 5 days a week with an average of at least 4 hours a day, was 56% in the PAP-NAP group and 17% in controls.

Retrospective Cohort Study

The same group of investigators (Ulibarri et al, 2020) conducted a retrospective chart review of 139 individuals who were diagnosed with OSA or upper airway resistance syndrome between 2011 and 2016 and had initially refused titration of PAP but accepted a trial of PAP with a PAP-NAP.¹² The most common risk factors for initial PAP rejection were depression,

insomnia, claustrophobia, and trauma exposure, while the most common indications for PAP-NAP were general reluctance, anxiety, and claustrophobia. The procedure averaged about 3 hours, which included 83 + 30 min of coaching and 107 + 57 min napping; 99% of individuals experienced expiratory pressure intolerance and a majority preferred an alternative PAP mode for the nap period. Use at follow-up was determined by renewal request for PAP supplies, retitration, clinic appointment or other contact with staff. The duration of use is unclear from the report, but at the time of follow-up 71% of individuals who had initially refused PAP were considered users and 29% were non-users.

Subsection summary: PAP-NAP

The evidence on the PAP-NAP includes 1 comparative trial with historical controls and a case series of individuals who were resistant to CPAP titration. These studies do not provide sufficient evidence to form conclusions on the efficacy of this approach in improving compliance with CPAP. The individual population in the comparative study was highly selected and the behavioral intervention may be dependent on the specific clinicians providing treatment. In addition, historical controls were used, and they were not well-matched to the study population. For these reasons, the internal validity and generalizability of the results are uncertain.

Nasal Expiratory Positive Airway Pressure

Evidence on nasal expiratory positive airway pressure (EPAP) includes a moderately sized RCT and a systematic review on the Provent device.

Systematic Reviews

A systematic review by Riaz et al (2015) identified 18 studies (N=920) that had data on pre- and postnasal EPAP.¹³ Study designs included 10 conference papers and 8 publications (case series, cohort studies, RCTs). For individuals included in the meta-analysis (n=345), AHI decreased from 27.32 to 12.78 events per hour ($p<.001$). For 359 individuals, ESS score modestly improved from 9.9 to 7.4 ($p<.001$). Data from the Berry et al (2011) RCT (described above) were not included in this meta-analysis because mean data were not reported. Response to the nasal EPAP was variable and inconsistent, and there were no clear characteristics (demographic factors, medical history, and/or physical exam finding) that predicted a favorable response.

Randomized Controlled Trials

Berry et al (2011) reported on an industry-sponsored multicenter, double-blind, randomized sham-controlled trial of EPAP.¹⁴ Two hundred fifty individuals with OSA and an AHI of 10 or more events per hour were randomized to nasal EPAP (n=127) or to a sham device (n=123) for 3 months. PSG was performed on 2 nights (device-on, device off, in a random order) at week 1 (92% follow-up) and after 3 months of treatment (78% follow-up). EPAP reduced median AHI from 13.8 to 5.0 events per hour (-52.7%) at week 1 and from 14.4 to 5.6 events per hour (-42.7%) at 3 months. This reduction in AHI in the treatment group was significantly greater (-7.3% at week 1, -10.1% at 3 months) than in the sham group. Over 3 months, the decrease in ESS score was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1-point difference in ESS score is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol individuals who had an AHI of 5 or more events per hour on the device-off PSG night. The oxygenation results (Oxygenation Desaturation Index and percent of total sleep time with oxygen saturation <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI

reduction to less than 10 events per hour (if device-off AHI was ≥ 10 events per hour), was greater in the EPAP group at 1 week (62% vs 27.2%) and at 3 months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of individuals in the EPAP group and by 34% of individuals in the sham group, with 7% of individuals in the EPAP group discontinuing due to adverse events. Overall, the validity of these results was limited by the high dropout rate, and the clinical significance of the results is uncertain.

Kryger et al (2011), in an open-label extension of the 2011 randomized study by Berry et al (2011), evaluated 12-month safety and durability of the treatment response in individuals who had an initially favorable response to EPAP.¹⁵ Included were 41 (32%) of the 127 individuals in the EPAP arm of the study who used the device for an average of at least 4 hours per night on at least 5 nights a week during months 1 and 2 and had at least a 50% reduction in AHI, or reduction to less than 10 events per hour, compared to the device-off PSG. Of the 51 (40%) of 127 eligible individuals, 41 enrolled in the extension study, and 34 (27%) of 127 were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events per hour; the percentage of individuals who met criteria for success was not reported. The arousal index was modestly decreased (from 23.9 to 19.0). After 12 months of treatment, the ESS score decreased from 11.1 to 6.0. The median percentage of reported nights used (entire night) was 89.3%. Device-related adverse events were reported by 42% of individuals, most frequently difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study was limited by its inclusion only of responders and by the potential for a placebo effect on the ESS score. However, the data suggested that some individuals might have responded to this device, and the individual compliance data might indicate a positive effect on daytime sleepiness that leads to continued use of the device in about 25% of individuals. Additional controlled studies are needed to distinguish between these alternatives.

Kureshi et al (2014) reported on a small (n=14) double-blind, pilot, crossover RCT of EPAP in children to evaluate efficacy and compliance with this new treatment.¹⁶ PSG with EPAP or a placebo device showed a significant mean improvement in Obstructive Apnea Index with EPAP (0.6 versus 4.2, $p=0.01$), but responses varied (3 did not improve, 2 worsened). No other measures were statistically significant in this trial. For responders who used the devices at home for 30 days, adherence was 83% of nights. ESS scores improved from 11 to 7 ($p=0.031$) and Obstructive Sleep Apnea-18 questionnaire scores improved from 50 to 39 ($p=0.028$). Other outcome measures did not improve significantly.

Sleeper et al. (2022) conducted a laboratory comparison to test the expiratory pressures generated by the following four expiratory positive airway pressure (EPAP) devices: ULTepap, Provent, Bongo Rx, and Theravent.³⁷ Measurement of the expiratory and inspiratory pressures were captured by a Respirationics digital pressure manometer. Prior to the measurement of each of the devices, the manometer was calibrated to zero. The authors found the expiratory pressures generated by ULTepap and Provent were similar, with ULTepap being slightly lower at all flow rates. The Bongo Rx and Theravent devices produced substantially lower backpressures than Provent and ULTepap, in addition to Bongo Rx having a significantly lower flow rate. In summary, the authors felt not all FDA cleared EPAP devices provide similar mechanical results and additional clinical trials comparing short- and long-term efficacy, patient satisfaction, and adherence are warranted. Limitations included lack of OSA specific outcomes and lack of clinical evidence of efficacy.

Oral and OroNasal Pressure Therapy

Randomized Controlled Trials

Lai et al (2019) reported a study with 22 individuals with OSA who were incomplete responders to an oral appliance (AHI > 5).¹⁷ They were assessed with the oral appliance plus either an oral or an oronasal EPAP. Both the oral and oral/nasal devices were studied in the same night (split night PSG); the order of the EPAP devices was randomized. Power analysis indicated that 20 participants would be sufficient to detect an AHI difference of 7 between conditions. Five individuals (23%) had at least a 50% reduction in total AHI with the oral EPAP compared to the oral appliance alone, while 10 individuals (45%) had a 50% reduction in AHI with the combined oral and nasal EPAP valves. Neither of these was statistically significant. Only 2 individuals (9%) achieved an AHI of less than 5 with the oral EPAP device compared to 9 (41%) with the combined oral and nasal valves. However, sleep efficiency was disrupted with the oronasal EPAP valves.

Subsection Summary: Nasal Expiratory Positive Airway Pressure

The evidence on nasal EPAP devices in individuals with OSA has been reported in smaller RCTs, an industry-sponsored RCT, and a systematic review that did not include the industry-sponsored RCT. The main finding of the industry-sponsored RCT was a decrease in AHI with a minor impact on oxygenation and ESS score. An oral EPAP device did not have significant benefit when added to an oral appliance in a small RCT.

eXciteOSA

eXciteOSA (previously named Snoozeal) is intended to reduce snoring and mild OSA by increasing tongue muscle tone with daytime neuromuscular electrical stimulation.

Prospective Cohort Studies

Two prospective single arm studies were identified, both instructed participants to use the device for 20 min daily for 6 weeks. Objective sleep parameters were measured by a Watch-PAT and use was tracked by the accompanying smartphone app. The time snoring greater than 40 dB (all snoring) was a primary outcome. Subjective decrease in snoring by the bed partner was measured by a Visual Analogue Scale (VAS), and the ESS and the Pittsburgh Sleep Quality Index (PSQI) were used to assess subjective sleepiness and quality of life.

Kotecha et al (2021) studied a prospective cohort of 75 habitual snorers who were treated with eXciteOSA.¹⁸ Individuals with a body mass index (BMI) greater than 35 and AHI greater than 15 were excluded. For the 70 individuals who completed the study, snoring time measured by the Watch-PAT decreased by 48% and bed partners reported an average reduction in snoring of 40%. The mean AHI decreased from 5.94 to 5.37 events per hour. The PSQI improved by approximately 1 point for both the participants (7.03 ± 3.13 to 5.92 ± 2.83 , $p = .004$) and bed partners (7.35 ± 2.76 to 6.33 ± 2.80 , $p = .029$). In the 38 individuals with mild OSA, AHI was reduced from 9.8 to 4.7 events/h, and the ESS improved from 9.0 to 5.1 ($p < .001$). Compliance with the protocol as measured by the app ranged from 59.5% to 95.2% (mean utilization 83.3%).

In a study by Baptista et al (2021), eXciteOSA was administered to 125 individuals with a complaint of snoring and an AHI less than 15 (no more than mild OSA), 50 participants had an AHI of less than 5 and were considered primary snorers.¹⁹ Only 1 participant withdrew due to inability to tolerate the treatment (gag reflex), and 115 participants completed the trial (92%). The mean reduction in the proportion of time with moderate or greater snoring decreased from 30.41% to 17.87% (41% reduction, $p < .001$). Bed-partner-reported snoring decreased from 6.1 to 3.7 ($p < .001$). ESS improved from 8.4 to 5.8 and the PSQI improved for both the participants

(7.16 to 5.75, $p < .001$, 95% CI 0.89–1.92) and bed partners (6.87 to 5.94, $p = .02$, 95% CI 0.15–1.68). The AHI was reduced from 6.85 to 5.01 ($p < .001$), a difference that is not clinically significant.

Subsection Summary: eXciteOSA

No controlled trials on eXciteOSA were identified. The evidence includes 2 prospective single arm studies in individuals with primary snoring or mild OSA. The available evidence suggests that when used for 20 min a day over 6 weeks, the treatment may reduce snoring. In the overall population, the effects on AHI were not clinically significant. For the subgroup of individuals with mild OSA, the improvement in AHI in these uncontrolled trials remained modest. With a mean ESS of less than 10, this group of individuals might not be considered symptomatic. Controlled studies are needed to evaluate whether individuals who meet criteria for treatable OSA improve and whether individuals would continue use after the 6 week trial period.

NightBalance Sleep Position Trainer

Systematic Review

For some individuals, apneic events occur predominantly when the individual is supine. Sleep position trainers for individuals with positional OSA are intended to reduce time on the back and can range from supine vibration alarm devices to tennis balls sewn into the back of night wear. A Cochrane review by Srijithesh et al (2019) evaluated positional therapy for obstructive sleep apnea.²⁰ The meta-analysis included 3 crossover studies with a vibration alarm and 5 with specially designed pillows or semi-rigid backpacks. The review found low to moderate evidence that CPAP was more effective than positional therapy in improving AHI ($n=72$), but positional therapy was more effective than no treatment for improving outcomes ($n=251$) and may have better adherence than CPAP. All of the studies were short-term and the long-term effect was uncertain.

Randomized Controlled Trials

Several RCTs have been reported on the FDA-cleared NightBalance Sleep Position Training device. The device vibrates when it detects a supine position and the vibration increases gradually until the individual changes position. Characteristics and results of RCTs are described in Tables 4 and 5. Limitations of the trials are described in Tables 6 and 7.

Eijsvogel et al (2015) compared the first generation sleep position trainer to "the tennis ball technique" with commercially available air pillows on the back in 55 participants.⁸ Both devices reduced supine position by a median of 100% and reduced the median supine AHI to 0 events/h at the 1 month sleep study. There were no significant differences between the groups for the ESS, VAS, and sleep-related quality of life data. Objective compliance data for the entire month showed that the median hours used per night was numerically higher but did not achieve statistical significance due to variability (6.5 vs 4.5, $p=.078$). There were significant increases in the percentage of individuals who used the device every day (51.7% vs 15.4%, $p=.005$) and in effective compliance, measured by use for at least 4 hours per night on at least 5 days per week (75.9% vs 42.3%, $p=.011$). Compliance in both groups decreased over the month of the study. Continued use after the month trial was not evaluated, and the clinical significance of an increase in compliance without a difference in sleepiness or quality of life is uncertain.

de Ruiter et al (2018) evaluated 12 month efficacy of the NightBalance Sleep Position Trainer compared to oral appliance therapy in a multicenter randomized trial of participants with positional OSA.¹⁵ This was a follow-up to a previously published 3-month study. There were no significant differences between the 2 groups in AHI, ESS, FOSQ, or the average hours of use per night. However, 41% of the participants had dropped out of the study by the 12 month follow-up due to adverse events or lack of efficacy, and results in the publication represent only those individuals who had remained in the study. Sensitivity analysis with intention-to-treat was reported in a supplement, and in the worst case scenario, AHI decreased by 1 with NightBalance and by 5.5 with the oral appliance. With intention-to-treat and last observation carried forward, the average hours of use per night decreased to 3.1 for NightBalance and 2.7 for the oral appliance (p=.522).

Berry et al (2019) compared the NightBalance Sleep Position Trainer to APAP in a 6-week randomized crossover trial in treatment naive individuals (N=117) with exclusive positional OSA.²¹ The investigators selected a non-inferiority margin of 5 events/h for the AHI endpoint and 30 minutes for adherence. The sleep position trainer achieved non-inferiority with a difference of 3.58 events/h. APAP was more effective than the Sleep Position Trainer in terms of the AHI (p<.001), but adherence was better with NightBalance (p <.001). There were no significant differences between the treatments for total sleep time, sleep efficiency, sleep latency, wake after sleep onset, or the duration of sleep stages. The ESS was statistically better in the APAP phase, although this did not achieve clinical significance. Post-hoc analysis of participants who had a baseline ESS score of greater than 10 showed that while both treatments improved the ESS, APAP was more effective (final ESS: 9.5 vs 11.5, p<.001). Individuals reported that the NightBalance device was easier to use and more comfortable and would choose this device, but thought that APAP was more effective in treating the sleep apnea.

Table 4. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Design	Participants	Interventions ¹	
					Active	Comparator
Eijsvogel et al (2015) ⁸	EU		Randomized parallel arm	55 individuals with mild to moderate symptomatic POSA who had been referred to a tertiary care center	4 weeks with the first generation NightBalance Sleep Position Trainer (n=29)	4 weeks with commercially available inflated airbags on the back (n=26)
de Ruiter et al (2018) ⁹	EU	2	Randomized parallel arm	99 individuals with mild to moderate POSA, defined as AHI $\geq$ 2 times nonsupine AHI and total AHI < 15 events/h	12 mo follow-up with NightBalance Sleep Position Trainer (n=48, 29 completed)	12 mo follow-up with OAT with an imbedded microchip to monitor usage (n=51, 29 completed)

Berry et al (2019) ²¹ (POSActive)	US	11	Randomized crossover	117 treatment naive individuals with exclusive POSA, defined as a supine AHI ≥ 2 times nonsupine AHI and a nonsupine AHI < 10 events/h; total AHI was at least 15 events/h (moderate to severe OSA).	6 weeks with the NightBalance Sleep Position Trainer	6 weeks with APAP
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AHI: apnea/hypopnea index; APAP: auto-adjusting positive airway pressure; CPAP: auto-adjusting; positive airway pressure; OAT: oral appliance therapy; OSA: obstructive sleep apnea; POSA: positional obstructive sleep apnea; RCT: randomized controlled trial.1 Number randomized; intervention; mode of delivery; dose (frequency/duration).

Table 5. Summary of Key RCT Results

Study	AHI (sd)	Adherence (sd)	ESS (sd)	Quality of Life (sd)
Eijsvogel et al (2015) ⁸		<i>Hours per Night (sd)</i>		<i>QSQ (sd)</i>
N	48	55	48	48
NightBalance	3.9 (0.4–30.8)	6.5 (5.5–7.2)	6.0 $\pm$ 3.6	5.4 $\pm$ 1.2 *
TBT	5.8 (0.2–23.1)	4.5 (1.1–7.0)	7.8 $\pm$ 4.3	4.8 $\pm$ 1.3
p		.078		
de Ruiter et al (2018) ⁹	<i>12 mo follow-up</i>	<i>Hours per Night (sd)</i>		<i>FOSQ (sd)</i>
N	58	57	46	30
NightBalance	7.1	5.2 (2.2)	7.0	19.0
OAT	5.0	5.0 (2.0)	4.0	17.7
p	.792	.743	.073	.864
Berry et al (2019) ²¹ (POSActive)		<i>Minutes per Night</i>		
NightBalance	7.29 (6.8)	345.3 (111.22)	8.27 (4.98)	17.32 (2.18)
CPAP	3.71 (5.1)	286.98 (128.9)	7.37 (3.98)	17.62 (1.87)
p	<.001	<.001	.007	.058

AHI: apnea/hypopnea index; CPAP: continuous positive airway pressure; ESS: Epworth sleepiness scale; FOSQ: functional outcomes of sleep questionnaire; OAT: oral appliance therapy; RCT: randomized controlled trial; SF-36: short-form 36; TBT: tennis ball technique (airbags); QSQ: Quebec Sleep Questionnaire.

Table 6. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
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Eijsvogel et al (2015) ⁸	4. Not all individuals would have qualified for treatment. The mean score on the Epworth Sleepiness Score was < 10.	4. This was a first generation device			1. There was no long-term follow-up after the 4 week intervention
de Ruiter et al (2018) ⁹					
Berry et al (2019) ²¹ (POSAtive)					1. There was no long-term follow-up after the 6 week cross-over phases.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use. b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest. c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively. d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported. e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 7. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Eijsvogel et al (2015) ⁸	3. Allocation concealment unclear	1, 2. Participants could not be blinded to treatment assignment and could bias the subjective measures.		6. Not intent to treat analysis		
de Ruiter et al (2018) ⁹	3. Allocation concealment unclear	1, 2. Participants could not be blinded to treatment assignment.	2. Individuals lost to follow-up were not counted as treatment failures in the primary analysis.	1, 2. High loss to follow-up; 59% of individuals completed the study		
Berry et al (2019) ²¹ (POSAtive)	3. Allocation concealment unclear	1, 2. Participants could not be blinded to treatment assignment.				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment. a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias. b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome

assessment; 3. Outcome assessed by treating physician. c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication. d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials). e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference. f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per individual; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Observational Studies

Van Maanen and de Vries (2014) conducted a prospective study in individuals with mild to moderate positional OSA.²² There were 145 individuals who were asked to use the Sleep Position Trainer for 6 months with the option to keep the device at the end of the study. However, the data could not be retrieved in 39 individuals, leaving 106 with objective data. The time spent supine decreased from 21% at baseline to 3% in the 53 participants (36%) who provided objective measurements at 6 months. Subjective measures (median ESS 11 to 8; PSQI 8 to 6; and FOSQ 87 to 103) were significantly improved compared to baseline, but only 66 participants out of the 145 (45%) completed the questionnaires. Analysis was per protocol rather than intent-to-treat, raising questions about the validity of the results. Regular use, defined as at least 4 hours a night over at least 5 nights, was 71.2% averaged over the trial period. Objective use of the device for at least 1 hour per night decreased from 106 individuals at the start of the study to less than 60 by 6 months. It is uncertain whether the number of individuals using the device would be as high as this outside of a trial.

Beyers et al (2018) invited individuals to participate in a 1 month trial of the sleep position trainer as part of a standard clinical pathway at a university hospital in the EU.²³ In order to qualify for the trial, individuals were required to have an overall AHI of > 5 events/h, a supine AHI at least twice as high as the non-supine AHI, and 10% to 90% of total sleep time spent in the supine position. Out of 101 individuals, 79 (78%) completed the 28 day trial period. There were 45 responders who had an overall reduction in Respiratory Event Index (REI) from 11.3 to 3.4 and a reduction in supine REI from 28.9 to 2.3. For the 44 individuals (43% of 101) who decided to purchase the device, 27 (27% of total) were considered responders. Reasons for not purchasing the device included persistent daytime sleepiness, intolerance to the vibrations, and preference for other treatment options. Due to the relatively low percentage of individuals who responded and chose to purchase the device, the investigators recommended a trial period. Treatment success over longer than the 1 month trial period was not evaluated. Similar findings were reported in a separate clinical study of 51 consecutive individuals with positional OSA who had a 1 month trial of the NightBalance device.²⁴ About half of individuals (n=27) were considered adherent during the trial, and half of those (n=13) wanted to purchase the device. Ten individuals had a higher response to the vibrations and were considered cured.

Subsection Summary: NightBalance Sleep Position Trainer

The evidence on the NightBalance Sleep Positioning Trainer Includes RCTs and single arm studies. The RCTs suggest that the device may be as effective as oral appliances and more comfortable than positive airway pressure in individuals with positional OSA. However, the studies are limited by a high dropout rate and short follow-up. A 6 month prospective study found that 64% of individuals used the sleep position trainer for more than 4 h per night, but another observational study found that only a quarter of individuals may be both able to tolerate the device and have a reduction in supine AHI in the short-term. Further study is needed to evaluate who may receive benefit and continue utilization after the trial period.

SUMMARY OF EVIDENCE

For individuals who have OSA who receive oral appliances, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. A diagnostic sleep study may be followed by a trial of APAP to evaluate efficacy and adjust pressure. APA or bilevel PAA may also be indicated if the individual is intolerant of CPAP. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments the evidence includes RCTs and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on nasal EPAP devices in individuals with OSA has been reported in prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the AHI, with minor impact on oxygenation, and a decrease in ESS score. One comparative trial with historical controls used a PAP-NAP to study individuals with complex insomnia resistant to CPAP titration or use. Additional study is needed to evaluate with greater certainty the efficacy of this intervention. One small RCT with 22 individuals found no benefit of an oral EPAP therapy device when added to an oral appliance. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2010 Input

In response to requests, the BCBSA received input from 1 physician specialty society and 6 academic medical centers (8 reviewers) for their 2010 policy update. The input focused on the sensors required for unattended home sleep studies and on diagnosis and treatment of OSA in children. In general, the reviewers supported the requirement that home monitors measure 4 parameters, including respiratory effort, airflow, and oxygen saturation, and that their use be restricted to adults. Some exceptions were noted for specific situations. The update included recommendations from reviewers regarding indications that are specific to pediatric patients.

2009 Input

In response to requests, the BCBSA received input from 5 physician specialty societies (6 reviewers) and 3 academic medical centers while their policy was under review in 2009. Professional society guidelines and position statements were also reviewed. In general, the input supported the use of PSG, portable sleep monitoring tests, multiple sleep latency test,

and CPAP for adults as described in the policy. The update included the reviewer's recommendations for clarifications and modifications to the policy statements.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Sleep Medicine

The American Academy of Sleep Medicine (AASM) also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA.²⁵ The levels of recommendation are "standard"(generally accepted individual-care strategy, with a high degree of certainty; level 1 to 2 evidence), "guideline"(moderate degree of clinical certainty; level 2 to 3 evidence), or "option" (uncertain clinical use; insufficient or inconclusive evidence).

Treatment with oral appliances (OA) is indicated for “ with mild to moderate OSA, who prefer OAs to CPAP, or who do not respond to CPAP, or are not appropriate candidates for CPAP, or who fail CPAP ... (Guideline).

- Mandibular repositioning appliance covers the upper and lower teeth.
- Tongue retaining device holds the tongue in a forward position.

The AASM and the American Academy of Dental Sleep Medicine (2015) published guidelines on the treatment of OSA and snoring with oral appliance therapy.²⁶ The two societies provided a recommendation of “standard” that sleep physicians consider prescription of oral appliances, rather than no treatment, for adults with OSA who are intolerant of CPAP therapy or prefer alternative therapy. The quality of evidence was rated as moderate. “Guideline” recommendations were provided for the use of custom, titratable appliance over non-custom oral devices, that qualified dentists provide oversight, that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, and that patients return for periodic office visits with a qualified dentist and a sleep physician.

American Academy of Pediatrics

The American Academy of Pediatrics (AAP; 2012) published guidelines on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting, which updated AAP's 2002 guidelines.^{27,28} AAP recommended that all children or adolescents be screened for snoring, and PSG be performed in children or adolescents with snoring and symptoms or signs of OSA as listed in the guideline. If PSG is not available, an alternative diagnostic test or referral to a specialist, may be considered (option). The estimated prevalence rates of OSA in children or adolescents ranged from 1.2% to 5.7%. Adenotonsillectomy was recommended as the first-line treatment for patients with adenotonsillar hypertrophy, and patients should be reassessed clinically postoperatively to determine whether additional treatment is required. High-risk patients should be reevaluated with an objective test or referred to a sleep specialist. CPAP was recommended if adenotonsillectomy was not performed or if OSA persisted postoperatively. Weight loss was recommended in addition to other therapy in patients who are overweight or obese, and intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

American Society of Metabolic and Bariatric Surgery

The American Society of Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA (reviewed in October 2015).²⁹ The guidelines noted that while some reports in the literature have recommended routine screening for OSA prior to bariatric surgery, other reports have suggested clinical screening only does not result in any increase in postoperative pulmonary complications after laparoscopic Roux-en-Y gastric bypass, and that most current surgical practices refer patients with clinical symptoms of OSA for PSG, but do not make this a routine preoperative test prior to bariatric surgery. The society provided, based on the evidence in the literature to date, the following guidelines on OSA in the bariatric surgery patient and its perioperative management:

1. "OSA is highly prevalent in the bariatric patient population....
4. [Patients with moderate to severe OSA] should bring their CPAP machines, or at least their masks, with them at the time of surgery and use them following bariatric surgery at the discretion of the surgeon.
7. Routine pulse oximetry or capnography for postoperative monitoring of patients with OSA after bariatric surgery should be utilized, but the majority of these patients do not routinely require an ICU [intensive care unit] setting.
8. No clear guidelines exist upon which to base recommendations for retesting for OSA following bariatric surgery...."

American Academy of Otolaryngology–Head and Neck Surgery

In 2017, the American Academy of Otolaryngology-Head and Neck Surgery published a position statement on the treatment of obstructive sleep apnea.³⁰ The academy states that tonsillectomy and adenoidectomy is the first line treatment in pediatric OSA. In most adults, CPAP is the first line treatment. Surgical procedures may be considered when PAP therapy is inadequate.

American Thoracic Society

The American Thoracic Society (2016) published a statement on the long-term effects and treatment of mild OSA in adults.³¹ The Society's systematic review concluded:

- Daytime sleepiness: subjective improvement with CPAP; unclear effect with non-CPAP therapies
- Quality of life: small improvements seen in different domains in different studies
- Neurocognition: treatment effects inconsistent.

American Heart Association

In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease.³² The treatment options for OSA and eligibility for their use are described in the statement and briefly summarized below:

- Positional therapy: "Indicated for positional sleep apnea defined by breathing events only (isolated) or predominantly in the supine posture often considered as supine AHI at least double the lateral AHI."
- Oral appliances: "Alternative to CPAP for mild to moderate OSA or in individuals who do not tolerate CPAP."

The statement also notes the following with regards to treatment:

"All individuals with OSA should be considered for treatment, including behavioral modifications and weight loss as indicated. Continuous positive airway pressure should be offered to individuals with severe OSA, whereas oral appliances can be considered for those with mild to moderate OSA or for continuous positive airway pressure-intolerant individuals. Follow-up sleep testing should be performed to assess the effectiveness of treatment."

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2017) reviewed the evidence on screening for OSA in adults and concluded that "the current evidence is insufficient to assess the balance and harms of screening for obstructive sleep apnea (OSA) in asymptomatic adults. Evidence on screening tools to accurately detect persons in asymptomatic populations who should receive further testing and treatment of subsequently diagnosed OSA to improve health outcomes is lacking, and the balance of benefits and harms cannot be determined."^{33,34}

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov identified over 300 studies on diagnosis and medical management of OSA.

Government Regulations

National:

N/A

Local:

CGS Administrators, LLC

Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611)

Original Effective Date: For services performed on or after 10/1/15

Revision Effective Date: For services performed on or after 08/07/2021

A custom fabricated mandibular advancement oral appliance (E0486) used to treat obstructive sleep apnea (OSA) is covered if criteria A - D are met.

- A. The beneficiary has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the beneficiary for obstructive sleep apnea testing.
- B. The beneficiary has a Medicare-covered sleep test that meets one of the following criteria (1 - 3):
 1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,

2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
 - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
 - b. Hypertension, ischemic heart disease, or history of stroke; or,
 3. If the AHI > 30 or the RDI > 30 and meets either of the following (a or b):
 - a. The beneficiary is not able to tolerate a positive airway pressure (PAP) device; or,
 - b. The treating physician determines that the use of a PAP device is contraindicated.
- C. The device is ordered by the treating physician following a review of the report of the sleep test. (The physician who provides the order for the ORAL APPLIANCE could be different from the one who performed the clinical evaluation in criterion A.)
- D. The device is provided and billed for by a licensed dentist (DDS or DMD).
- If all of these criteria (A-D) are not met, the custom fabricated oral appliance (E0486) will be denied as not reasonable and necessary.

Refer to the NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the Policy Article for information about coverage for appliances that achieve their effect through positioning of the tongue (A9270).

A prefabricated oral appliance (E0485) will be denied as not reasonable and necessary. There is insufficient evidence to show that these items are effective therapy for OSA.

Custom fabricated mandibular advancement devices that have not received a written coding verification from the Pricing, Data Analysis, and Coding (PDAC) contractor will be denied as not reasonable and necessary.

CGS Administrators, LLC

Local Coverage Article: Oral Appliances for Obstructive Sleep Apnea - Policy Article (A52512) Original Effective Date 10/01/2015; Revision Effective Date 08/08/2021

Oral appliances used to treat obstructive sleep apnea (OSA) are covered under the Durable Medical Equipment benefit (SSA 1861(s) (6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that must be met.

Oral appliances generally are classified as dental devices and are not classified as durable medical equipment. The following items (not all-inclusive) are considered to be dental devices and will be denied as non-covered, not DME:

- Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders
- Tongue retaining devices used to treat OSA and/or snoring
- All oral appliances used only to treat snoring without a diagnosis of OSA
- Oral appliances used to treat other dental conditions
- Oral appliances that require repeated fitting and/or adjustments, beyond the first 90-days, in order to maintain fit and/or effectiveness

All follow-up care, including fitting, adjustments, modifications, professional services (not all-inclusive) required during the first 90 days after provision of the oral appliance are considered to be included in the payment for device. Claims for these will be denied as not separately payable.

After the initial 90-day period, adjustments, modifications and follow-up visits are not eligible for coverage under the DME benefit and are therefore not within the jurisdiction of the DME MAC.

Repairs are covered for items that meet the coverage criteria. To repair means to fix or mend and to put the item back in good condition after damage or wear. Repairs are covered when necessary to make the item serviceable. If the expense for repairs exceeds the estimated expense of purchasing another item, no payment can be made for the excess.

Oral appliances are eligible for replacement at the end of their 5-year reasonable useful lifetime (RUL). These items may be replaced prior to the end of the 5-year RUL in cases of loss, theft, or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). Replacement due to wear-and-tear as the result of everyday use will be denied as statutorily non-covered prior to the expiration of the 5-year RUL.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Actigraphy
 - Home Cardiorespiratory Monitoring - Pediatric
 - Obstructive Sleep Apnea and Snoring, Surgical Management
 - Positive Pressure Airway Devices
 - Diagnosis of Sleep Disorders
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 12, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/23	4/26/23		• 4/18/23 Followed BCBSA – relevant information was developed from the information from the JUMP Sleep Disorders – Diagnosis and Medical Management. This new JUMP policy is now called Medical Management of Obstructive Sleep Apnea Syndrome. We have a separate JUMP policy called Diagnosis of OSA Syndrome. • Under Medical Policy Statement: ○ Moved Diagnosis Language to JUMP policy called Diagnosis of OSA Syndrome. ○ Added an inserted nasal valve, used under Nasal Expiratory Positive Airway Pressure for clarification purposes. ○ Removed Positional therapy devices and added The use of sleep positioning trainers with vibration, and for the treatment of positional OSA for clarification purposes. • Added the below sentences to the MPS: ○ The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered experimental/investigational. ○ The use of daytime electrical stimulation of the tongue is considered

			experimental/investigational for the treatment of OSA. • Under Inclusionary and Exclusionary Guidelines: ○ Moved Diagnosis Language to JUMP policy called Diagnosis of OSA Syndrome. ○ Under Inclusions: added For Intraoral Appliances (Tongue-Retaining Devices or Mandibular advancing/positioning devices. ○ Added Diagnosis of under OSA. ○ Updated the language in this bullet in bold to align with BCBSA: an AHI, RDI or REI of at least 5 events per hour in an individual with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke), AND ○ Under Exclusions: added The use of intraoral appliances that do not meet the above criteria are considered experimental/investigational for the treatment of OSA. Added for the treatment of OSA for clarification purposes under Palate and mandible expansion devices for the treatment of OSA are considered experimental/investigational. ○ Removed Positional therapy devices and added The use of sleep
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			positioning trainers with vibration, and for the treatment of positional OSA for clarification purposes. ○ Policy Guidelines section moved to under Description/Background section. • Minor editorial refinements – updated patients to individuals. • Vendor: BCBSM/ BCN: Northwood. • References added. • Policy statements unchanged. • Title updated from Medical Management of Obstructive Sleep Apnea Syndrome to Medical Management of Obstructive Sleep Apnea Syndrome (Oral Appliances and Novel Therapies) • Added K1001 under E/I as the policy discuss the use of sleep positioning trainers with vibration, and for the treatment of positional OSA are considered experimental/investigational. (ky)
9/1/23	6/13/23		• Added new code A7049 Expiratory positive airway pressure intranasal resistance valve EFD 4/1/23 per code update as E/I. ○ Added the device ULTepap™ by BRYGGS Medical, LLC for this code to the JUMP policy. • Removed NCD for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1) and LCD: Polysomnography and Other Sleep Studies (L36839) as this JUMP policy is for Medical Management of OSA Syndrome. • Going forward this policy will continue to be reviewed at April JUMP. • Vendor: Northwood. (ky)

Next Review Date: 2nd Qtr, 2024

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 6/1/97	Revised: 6/28/01
BCBSM: 1/1/97	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE

POLICY: MEDICAL MANAGEMENT OF OBSTRUCTIVE SLEEP APNEA SYNDROME (ORAL APPLIANCES AND NOVEL THERAPIES)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, policy criteria apply.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.