

<b>8.01.67</b>	<b>Medical Management of Obstructive Sleep Apnea Syndrome</b>		
<b>Original Policy Date:</b>	October 1, 2022	<b>Effective Date:</b>	March 1, 2024
<b>Section:</b>	8.0 Therapy	<b>Page:</b>	Page 1 of 40

## Policy Statement

### Medical Management

- I. Continued positive airway pressure ([CPAP](#)) (or Auto-adjusting positive airway pressure [APAP]) may be considered **medically necessary** in adult or pediatric individuals with [clinically significant obstructive sleep apnea \(OSA\)](#), provided that diagnosis was based on the performance of an [approve](#) diagnostic study.
- II. Bilevel positive airway pressure (BiPAP) may be considered **medically necessary** with **both** of the following:
  - A. Individual has [clinically significant OSA](#)
  - B. Individual failed a prior trial of CPAP or whom BiPAP is found to be more effective in the [sleep lab](#)
- III. [Replacement of a PAP device](#) after the warranty period (usually 2-5 years) may be considered **medically necessary** with **all** of the following:
  - A. Documentation that the device is no longer functioning properly
  - B. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
  - C. Documentation of current compliance prior to the problem with the machine
  - D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)
  - E. Documentation the device is out of warranty
- IV. [Replacement of a PAP device](#) within the warranty period may be considered **medically necessary** with **all** of the following:
  - A. Documentation that the device is no longer functioning properly
  - B. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
  - C. Documentation of current compliance prior to the problem with the machine
  - D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)
  - E. Documentation that the cost of repairs would exceed that of replacement
- V. A single oral appliance (tongue-retaining devices or mandibular advancing/positioning devices) may be considered **medically necessary** in adults with [clinically significant OSA](#) when **all** of the following conditions have been met:
  - A. Initial or continued use of CPAP is [clinically not tolerated or is refused by the patient](#)
  - B. The device is prescribed by a treating provider
  - C. The device is custom-fitted by qualified dental personnel
  - D. There is documentation of absence of temporomandibular dysfunction or periodontal disease
  - E. Provider has reviewed, completed and signed an [OSA Oral Appliance Therapy Check-off List](#) (signed copy attached to request in addition to appropriate medical record documentation supporting the check list)
- VI. [Replacement of an oral appliance](#) (OA) *after* the warranty period (usually 3 years) may be considered **medically necessary** with **all** of the following:

- A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate
  - B. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
  - C. Documentation of current compliance prior to the problem with the OA
  - D. Documentation of benefit from the use of the OA (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)
  - E. Provider has reviewed, completed and signed an [OSA Oral Appliance Therapy Check-off List](#) (signed copy attached to request)
- VII. [Replacement of an oral appliance](#) (OA) *within* the warranty period may be considered **medically necessary** with **all** of the following:
- A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate
  - B. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
  - C. Documentation of current compliance prior to the problem with the OA
  - D. Documentation of benefit from the use of the OA
  - E. Documentation that the cost of repairs would exceed that of replacement
  - F. Provider has reviewed, completed and signed an [OSA Oral Appliance Therapy Check-off List](#) (signed copy attached to request)
- VIII. [Replacement of an oral appliance](#) due to changes in dental alignment may be considered **medically necessary** with **all** of the following:
- A. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
  - B. Provider has reviewed, completed and signed an [OSA Oral Appliance Therapy Check-off List](#) (signed copy attached to request)
  - C. Initial or continued use of CPAP is not tolerated or is refused by the patient
  - D. The device is prescribed by a treating provider
  - E. The device is custom fitted by qualified dental personnel
  - F. There is documentation of absence of significant temporomandibular dysfunction and periodontal disease
  - G. Needed after completion of orthodontic treatment that was prescribed and supervised by an orthodontist
- IX. The following are considered **investigational**:
- A. Nasal expiratory positive airway pressure (EPAP)
  - B. Oral pressure therapy devices
  - C. Mandibular/palatal expansion devices for the treatment of OSA
  - D. The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP)
  - E. The use of a sleep positioning trainer with vibration
  - F. The use of daytime electrical stimulation of the tongue
  - G. The use of CPAP, bi-level positive airway pressure, APAP, ASV and intraoral appliances that do not meet the above criteria for the treatment of OSA
  - H. Mandibular repositioning (daytime), bruxism and anti-snoring oral appliances for the treatment of OSA

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

### Home Sleep Apnea Test Devices

American Academy of Sleep Medicine (AASM) updated their guidelines in 2019 to recommend devices using BOTH a respiratory and abdominal belt (dual belt). Heart rate is no longer required. In addition, devices using PAT technology (e.g., WatchPAT) are also recommended. However, some other devices are considered to be acceptable, including some with single belts and some using different technology (using CPT 95806). The WatchPAT device uses CPT code 95800, and is now allowed as an acceptable device choice.

New devices using dual respiratory effort belts (chest and abdomen) should use CPT code G0400 since there is no heart rate. Code 95801 should not be used since it does not have the required types of channels.

Oximetry may be noted by the terms pulse oximetry (SpO<sub>2</sub>), oxygen saturation or CO-oximetry (measures carbon monoxide [CO] in addition to oxygen saturation).

BSC approval for all OSA therapeutic devices (including CPAP, APAP, bilevel positive airway pressure [BiPAP] and oral appliances) is based on the acceptable performance of an initial sleep apnea diagnostic test.

### Sleep Lab Test

If the request for CPT code 95810 is approved and the sleep study meets Blue Shield of California (BSC) Medical Policy requirements for a split night sleep study with CPAP titration during the study, please submit the claim for CPT code 95811 instead of CPT code 95810. Separate prior authorization for 95811 is not needed under these circumstances.

### Definition of 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.

The following are generally accepted measures of OSA severity in adults:

- **None/minimal:** AHI, RDI, or REI less than 5 events/hour
- **Mild:** AHI, RDI, or REI greater than or equal to 5 events/hour but less than 15 events/hour
- **Moderate:** AHI, RDI, or REI greater than or equal to 15 events/hour but less than 30 events/hour
- **Severe:** AHI, RDI, or REI greater than or equal to 30 events/hour

### Clinically Significant OSA in an adult

Includes either of the following:

- An Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), or Respiratory Event Index (REI) of at least 15 events per hour
- An AHI, RDI, or REI of at least 5 events per hour in a patient with excessive daytime sleepiness (as determined by standard sleep questionnaires such as the Epworth Sleepiness Scale >10 or the Berlin Questionnaire with a score of at least 2 in Category 2) or hypertension

Auto-adjusting positive airway pressure (APAP) may be considered medically necessary for the titration of pressure in adults with clinically significant OSA.

### Hypertension

Systolic BP  $\geq$ 140 or diastolic BP  $\geq$ 90, or on current medical treatment for hypertension.

### Risk Factors for Obstructive Sleep Apnea

Although not an exclusive list, individuals with all of the following symptoms are considered to be at high risk for OSA:

- habitual snoring;
- observed apneas;
- excessive daytime sleepiness;
- a body mass index (BMI) greater than 35 kg/m<sup>2</sup>.

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

Other risk factors for OSA include the following:

- Abrupt awakenings accompanied by gasping or choking
- Awakening with a dry mouth or sore throat
- Morning headache
- Impaired daytime concentration
- Mood volatility
- Nocturnal diaphoresis
- Decreased libido
- Enlarged neck size: males: 16.5 inches (43 cm); females: 15 inches (38 cm)
- Mallampati 4 classification

### Obesity-Hypoventilation Syndrome

Defined as daytime alveolar hypoventilation (awake arterial P<sub>CO2</sub>>45 mm Hg or serum bicarbonate  $\geq$ 27) among patients with body mass index  $\geq$ 30 kg/m<sup>2</sup> in the absence of other causes of hypoventilation.

### Sleep Questionnaires

The following sleep questionnaires (all self-answered by the patient) attempt to quantify the probability of having OSA:

- Epworth Sleepiness Scale: Comprised of eight questions with a maximum score of 24. A score of greater than 10 indicates moderate to high probability of OSA.
- Berlin Questionnaire: Comprised of 10 questions and three scoring categories. Two or more positive categories indicate a high probability of OSA.
- STOP-BANG: Comprised of eight questions. A "yes" answer on three or more questions indicates a high probability of OSA. The STOP-BANG questionnaire, a method developed for nonsleep specialists, assesses 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] >30 events per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is inadequate for the diagnosis of OSA. Therefore, a follow-up polysomnography (PSG) or home sleep apnea test would still be required to confirm or exclude a diagnosis of OSA.

### Obstructive Sleep Apnea in Children

The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a BMI greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI or RDI greater than 1.5 events per hour is considered abnormal (an AHI or RDI greater than or equal to 10 events per hour may be considered severe). 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.

### Significant Weight change

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.

### Specialist Training

Treatment of individuals diagnosed with obstructive sleep apnea (OSA) should be initiated and monitored by a professional trained 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).

### Split-Night Studies

American Academy of Sleep Medicine practice parameters (2005) have indicated that a split-night study (initial diagnostic PSG followed by CPAP titration during PSG on the same night) is an alternative to one full night of diagnostic PSG followed by a second night of titration if the following 4 criteria are met:

1. An AHI of at least 40 events per hour is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI between 20 and 40 events per hour, based on clinical judgment (e.g., if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP-level requirements, based on split-night studies, may be less accurate than in full-night calibrations.
2. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).
3. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM sleep, including REM sleep with the patient in the supine position.
4. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder is confirmed, but criteria 2 and 3 are not met.

Note: A split-night study, in which moderate-to-severe OSA is documented during the first portion of the study using PSG, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP and should be done unless documentation is provided why it cannot or was not done.

### Categorization of Polysomnography and Portable Monitoring

Full correspondence does not exist between CPT codes and the most current categorization scheme for the different types of studies. The 2005 practice parameters from the American Academy of Sleep Medicine list 4 types of monitoring procedures: type 1, standard attended in-lab comprehensive PSG; type 2, comprehensive portable PSG; type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of 4 or more channels of monitoring; and type 4, continuous single or dual bioparameters, consisting of 1 or 2 channels, typically oxygen saturation, or airflow. Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and PSG are often used interchangeably. CPT coding distinguishes between sleep studies that do not include electroencephalographic (EEG) monitoring, and PSG, which includes EEG monitoring. PSG is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the patient's home. There are no specific codes for remotely monitored home sleep studies. They would likely be reported with the CPT code for the sleep study with the GT

modifier ("via interactive audio and video telecommunications systems") appended. There is no CPT code for "unattended" PSG.

Cardiorespiratory sleep studies without EEG may be called polygraphic studies and can be attended or unattended by a technologist. CPT codes 95807 and 95806 distinguish polygraphic sleep studies that are attended or unattended, but there are no codes that distinguish between type 3 and type 4 sleep studies. A wide variety of portable monitors and proprietary automated scoring systems are being tested and marketed, but the optimum combination of sensors and scoring algorithms is currently unknown. Previous recommendations were that the portable monitoring device have 4 channels (oxygen saturation, respiratory effort, respiratory airflow, heart rate) and permit review of the raw data. Type 4 monitors with fewer than 4 channels are still not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional trained in sleep medicine to detect artifacts and data loss.

### **Continuous Positive Airway Pressure (CPAP)**

Note: Blue Shield of California follows the Medicare Durable Medical Equipment Regional Carrier (DMERC) rules with respect to the usual medically necessary quantity of supplies for PAP devices.

Examples of failed CPAP include but are not limited to:

- Claustrophobia
- Inability to breathe through the nose
- Patient intolerance
- Discomfort or pain
- Patients requiring high pressures of CPAP (greater than 10 cm H<sub>2</sub>O) complaining of pressure discomfort

Coverage for the following (in the diagnosis of OSA) may depend upon the applicable health benefit plan definition of medical necessity. Many health plans administered by Blue Shield contain definitions of medical necessity which include a cost comparison component. For those plans, Blue Shield will apply medical necessity criteria. In accordance with Blue Shield's medical necessity criteria, if there are two or more medically necessary services that may be provided for an illness, injury or medical condition, Blue Shield will provide benefits based on the most cost effective service.

### **Compliance**

Standard compliance guidelines require proof of using the device for a minimum of 4 hours per day at least 22 days out of a consecutive 30 day period within the preceding 90 days (in the past 3 months). For most devices, printouts of data from the devices are needed. For OAs, an attestation from the patient can be allowed.

### **CPAP and Oral Appliance**

CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for patients with severe OSA, because oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-to-moderate OSA. Therefore, it is particularly important that patients with severe OSA have an initial trial of CPAP and that all reasonable attempts are made to continue treatment with CPAP, prior to the decision to switch to an oral appliance. A repeat sleep apnea test is not required if prior test results showing the need for the device is provided.

### **Replacement of a PAP device**

A repeat sleep apnea test or trial period is not required if prior test results showing the need for CPAP is provided.

**Coding**

The miscellaneous DME code E1399 is sometimes submitted as an extra charge for setup, training and instruction in the use of APAP. These services are included in payment for the device. They do not need to be addressed separately as they are covered by claims editing rules when a claim is made for payment.

**HCPCS Codes**

There is 1 HCPCS code identifying a CPAP device, E0601, and 2 HCPCS codes for bilevel positive airway pressure (BiPAP) devices, E0470 and E0471. HCPCS codes do not distinguish among fixed CPAP or BiPAP devices and auto-adjusting CPAP devices.

**Effective April 1, 2023**, there is a new HCPCS code for a single-patient, reusable Expiratory Positive Airway Pressure (EPAP) device for the treatment of mild to moderate OSA:

- **A7049**: Expiratory positive airway pressure intranasal resistance valve

**Effective January 1, 2024**, The HCPCS codes **K1028** and **K1029** are being **deleted** and will be **replaced** by the following codes:

- **E0492**: Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
- **E0493**: Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply

**Effective January 1, 2024**, The HCPCS code **K1001** is being **deleted** and will be **replaced** by the following code:

- **E0530**: Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type

The system would be reported using code E0600 - Respiratory Suction Pump, Home Model, Portable or Stationary, Electric and code A7002 - Tubing, Used with Suction Pump, Each.

Refer to Blue Shield of California Medical Policy: Home Apnea Monitors for further information on neonatal home cardiorespiratory monitoring (CPT codes 94772-94777). These codes are not appropriate for the diagnosis of sleep apnea in children.

The following services are considered **inclusive** to the oral appliance: 21083, 70486, 70487, 76380, 97763, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, and 99215.

**Description**

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous positive airway pressure (CPAP) during sleep. Novel treatments include nasal expiratory positive airway pressure (EPAP) and oral pressure therapy.

**Related Policies**

- Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

A variety of oral appliances have been cleared for marketing by the 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 Sleep Well Smartrusion, 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 1.

**Table 1. Novel Devices for OSA Diagnosis and Treatment**

Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
<i>Diagnosis</i>					
<b>SleepImage System</b>	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
<i>Treatment</i>					
<b>Provent®</b>	Ventus Medical	Nasal expiratory resistance valve.	K102404	OHP	2010
<b>Winx™</b>	Apnicure, Inc	Nasal expiratory resistance valve.	K122130	OZR	2012
<b>mRNA Appliance®</b>	BioModeling Solutions	Expandable oral appliance for the treatment of snoring and mild-to-moderate OSA	K130067	LRK	2014
<b>NightBalance Lunoa System</b>	Philips	The positional sleep trainer is worn with an elasticized chest strap, and is intended to keep patients with positional obstructive sleep apnea from sleeping in the supine position.	K180608	MYB	2018
<b>eXciteOSA®</b>	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.	K223446	QNO	2021



Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
Respire Clear	Respire Medical, LLC	The device is an oral appliance used in the treatment of mild to moderate OSA. It helps move a patient's jaw forward, thus opening their airways, and allowing them to breathe more easily throughout the night.	K214096	LRK; LQZ	2022

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

## Rationale

### 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 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 patients 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. The snoring abruptly ceases during the apneic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. 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, heavy equipment), while OSA in children may result in neurocognitive impairment and behavioral problems.

Cardiovascular and pulmonary systems can also be affected by OSA.<sup>1</sup> 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 patients 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, 20% have mild OSA, and the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease.<sup>1</sup>

#### Diagnosis

Definitions of terms and scoring criteria for OSA are presented in Table 2. 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 patients. The criterion standard for a diagnosis of sleep disorders is a polysomnogram performed in a sleep laboratory.<sup>2</sup> A standard polysomnogram includes electroencephalogram (EEG), submental electromyogram, and electrooculogram (to detect rapid eye movement 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 additional PSG for CPAP titration.

A variety of devices have also been developed specifically to evaluate OSA at home. They range from portable full PSG systems to single-channel oximeters. Available devices evaluate different parameters, which may include oximetry, respiratory and cardiac monitoring, and sleep/wake activity, but most portable monitors do not record EEG activity.

**Table 2. Definitions of Terms and Scoring Criteria for OSA**

Terms	Definition
<b>Respiratory event</b>	
<b>Apnea</b>	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.
<b>Hypopnea</b>	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% arterial oxygen desaturation (depending on 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.
<b>RERA</b>	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.
<b>Respiratory event reporting</b>	
<b>AHI</b>	The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep.
<b>RDI</b>	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.
<b>REI</b>	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.
<b>OSA</b>	Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
<b>Mild OSA</b>	In adults: AHI or RDI of 5 to <15. In children: AHI $\geq$ 1.0 to <5
<b>Moderate OSA</b>	AHI or RDI of 15 to <30; Children: AHI of $\geq$ 5 to <10
<b>Severe OSA</b>	Adults: AHI or RDI $\geq$ 30; Children: AHI of $\geq$ 10
<b>UARS</b>	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.
<b>Positive airway pressure</b>	
<b>APAP</b>	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP
<b>PAP</b>	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.
<b>PAP failure</b>	Usually defined as an AHI >20 events per hour while using CPAP.
<b>PAP intolerance</b>	CPAP use for <4 hours per night for $\geq$ 5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in patients 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

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure (PAP) therapy (i.e., fixed CPAP, bilevel PAP, or auto-adjusting positive airway pressure [APAP]) during sleep. This evidence review addresses established and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (BioModeling Solutions), eXciteOSA (Signifier Medical Technologies), NightBalance Sleep Position Trainer (Phillips), Provent, and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA.

Surgical management of OSA (i.e., adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in Blue Shield of California Medical Policy: Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome (Surgical treatment of snoring and obstructive sleep apnea syndrome).

### **Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

### **Positive Airway Pressure Devices**

#### **Clinical Context and Therapy Purpose**

The purpose of positive airway pressure (PAP) 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 following PICO was used to select literature to inform this review.

#### ***Populations***

The relevant population of is individuals with OSA.

**Interventions**

The therapy being considered is various types of PAP therapy (i.e., fixed continuous positive airway pressure [CPAP], bilevel PAP, or auto-adjusting positive airway pressure [APAP]) during sleep. CPAP involves the administration of air, usually through the nose, by an external device at a fixed pressure to maintain the patency of the upper airway. Bilevel PAP is similar to CPAP, but these devices are capable of generating 2 adjustable pressure levels for inspiration and expiration. APAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been hypothesized that both bilevel PAP and APAP are more comfortable for the patient and thus might improve patient compliance or acceptance.

**Comparators**

The following therapy is currently being used to make decisions about the treatment of OSA: weight loss, position therapy, and CPAP or its variants. The major limitation of PAP therapy is poor patient 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 patients 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 $\geq 4$ 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 patients 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 $\geq 10$ is considered excessively sleepy. A decrease of 2 points is considered the MID. <sup>3</sup>
FOSQ	30 questions	Disease-specific QOL questionnaire that evaluates functional status related to excessive sleepiness	A score of $\geq 18$ is the threshold for normal sleep-related functioning, and a change of $\geq 2$ 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

#### Systematic Reviews

The American Academy of Sleep Medicine (AASM) commissioned a task force (Patil et al, 2019) to conduct an updated systematic review and meta-analysis of studies for the AASM 2019 guidelines on PAP for the treatment of OSA.<sup>4,5</sup> Meta-analyses of 184 studies indicated that PAP use leads to clinically significant reductions in disease severity (–23 events/hour; 95% confidence interval [CI], –29 to –18 events/hour), both subjective and objective sleepiness, daytime and nighttime blood pressure, and motor vehicle accidents, and improved sleep-related quality of life (QOL). The overall quality of evidence for the outcome of sleepiness was high and the overall quality of evidence for sleep-related QOL and for blood pressure was moderate. The quality of evidence on the effect of PAP on cardiovascular events and mortality was low to moderate, with benefits reported in non-randomized studies but not in RCTs. The task force concluded that the potential benefits of CPAP outweighed the harms in symptomatic patients. PAP initiation in the home had equivalent effects on patient outcomes compared to in-laboratory titration, and there were no clinically significant differences in patient outcomes with the use of auto-adjusting or bilevel PAP compared with standard continuous PAP. Adherence to PAP was improved with the use of educational, behavioral, troubleshooting, and telemonitoring interventions.

Balk et al (2011) conducted a comparative effectiveness review for the Agency for Healthcare Research and Quality (AHRQ) on the diagnosis and treatment of OSA in adults. The review concluded that the strength of evidence for CPAP for OSA was moderate based on the large magnitude of effect on the intermediate outcomes of the AHI, ESS score, and arousal index, even though there was weak evidence demonstrating an effect of CPAP on clinical outcomes.<sup>6</sup> In addition, reviewers found moderate evidence that APAP and fixed-pressure CPAP result in similar levels of compliance (hours used per night) and treatment effects for patients with OSA. There was moderate evidence that CPAP is superior to mandibular advancement devices (MADs) in improving sleep study measures. Evidence-based guidelines from the AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals.<sup>7,8,9,10</sup> As indicated in the AHRQ report, increased compliance with APAP devices has not been well-documented in clinical trials.<sup>11,12,13</sup> Thus, the issues associated with APAP are similar to those for bilevel PAP.

Yu et al (2017) conducted a meta-analysis assessing the association between PAP and cardiovascular events and death.<sup>14</sup> They included 10 trials with a total of 7266 patients with sleep apnea. There were 356 major adverse cardiovascular events and 613 deaths observed during follow-up (range, 6 to 57 months). The analysis found no significant association of PAP with a composite outcome of acute coronary syndrome events, stroke, or vascular death (relative risk, 0.77; 95% CI, 0.53 to 1.13). Trials were grouped according to adherence to PAP (<4 vs ≥4 hours/day), type of sleep apnea (obstructive vs. central), and type of PAP (CPAP vs. adaptive servo-ventilation). Meta-regression identified no association between PAP with outcomes for different levels of apnea severity, follow-up duration, or adherence to PAP. As reported by McEvoy et al (2016), the largest trial included in the meta-analysis was the Sleep Apnea Cardiovascular Endpoints RCT, which found no benefit of CPAP on the primary composite outcome of death or hospitalization for cardiovascular events in 2717 adults with moderate-to-severe OSA and cardiovascular disease who were followed for a median of 44 months.<sup>15</sup> With a mean duration of adherence to CPAP therapy of 3.3 hours per night, CPAP

significantly reduced daytime sleepiness (adjusted difference in ESS score, -2.5; 95% CI, -2.8 to -2.2;  $p < .001$ ) and improved health-related QOL and mood. Lisan et al (2019) reported 11-year follow-up of a cohort of 392 patients from the Sleep Heart Health Study who had obesity and severe OSA.<sup>16</sup> For the 81 patients who were prescribed PAP therapy, the propensity-matched hazard ratio for all-cause mortality was 0.58 (95% CI, 0.35 to 0.96) compared to matched patients who did not receive a prescription for PAP. Survival curves indicated that the difference in mortality appeared 6 to 7 years after initiation of PAP. Exploratory analysis indicated that PAP might also be associated with a lower risk of cardiovascular mortality.

### Randomized Controlled Trials

Monitoring of APAP use by daily transmission to a web-based database and review by a research coordinator has been shown to improve compliance to PAP therapy (191 min/day vs. 105 min/day).<sup>17</sup> For the telemedicine arm of this randomized trial, as reported by Fox et al (2012), the research coordinator reviewed the transmitted data daily and contacted the patient if any of the following were present: mask leak greater than 40 L/min for more than 30% of the night, less than 4 hours of use for 2 consecutive nights, machine-measured AHI of more than 10 events per hour, and 90th percentile of pressure greater than 16 cm H<sub>2</sub>O. Evaluation by their physician sleep specialist after 3 months of therapy showed a similar modest decrease in AHI for the 2 groups (1.6 for telemedicine vs. 0.7 for controls).

### Cohort Studies

An improvement in postoperative outcomes with CPAP was suggested by Mutter et al (2014) in a matched comparison of patients with OSA who had been diagnosed prior to surgery (2640 surgeries), those not diagnosed until up to 5 years after surgery (1571 surgeries), and 16277 surgeries for patients without a diagnosis of OSA over 21 years of available data.<sup>18</sup> In multivariate analysis, the risk of respiratory complications was increased for both diagnosed and undiagnosed OSA patients compared with controls (odds ratio, 2.08;  $p < .001$ ). The risk of cardiovascular complications, primarily cardiac arrest and shock, was higher in OSA patients not diagnosed until after surgery (relative risk, 2.20; 95% CI, 1.16 to 4.17;  $p = .02$ ), but not in those diagnosed prior to surgery (relative risk, 0.75; 95% CI, 0.43 to 1.28;  $p = .29$ ); the difference between groups was statistically significant ( $p = .009$ ). There was a significant trend toward a higher risk with increasing OSA severity. Study limitations included the inability to determine whether CPAP was used perioperatively, and, because body mass index could not be determined, potential confounding from the close association between obesity and OSA.

### Section Summary: Positive Airway Pressure Devices

PAP devices are accepted therapies for OSA. Studies have suggested that both CPAP and APAP are associated with improvements in sleep architecture. Although PAP has been associated with an improvement in intermediate outcomes in multiple studies, it has not been shown to improve hard cardiovascular outcomes. Interpretation of this finding is limited by the duration of follow-up (from 6 to 57 months) and mean CPAP use (<4 hours per night in the largest studies). Eleven-year follow-up of obese patients with severe OSA from the Sleep Heart Health Study found a reduction in all-cause mortality with PAP use which appeared after 6 to 7 years.

### Oral Appliances

#### Clinical Context and Therapy Purpose

The purpose of oral appliances in individuals who have OSA is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

#### Populations

The relevant population of is individuals with OSA.

### ***Interventions***

The therapy being considered is oral appliances during sleep.

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 patient by a dental laboratory or similar provider.

### ***Comparators***

The following therapy is currently being used to make decisions about the treatment of OSA: weight loss, position therapy, and CPAP or its variants.

### ***Outcomes***

The general outcomes of interest are the number of apneas or hypopneas during sleep, measured by the AHI, and subjective symptoms of sleepiness, typically measured with the ESS or the FOSQ. Additional health outcome measures relevant to OSA are summarized in Table 3 above.

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**

#### **Systematic Reviews**

In the AHRQ report (2011) on the diagnosis and treatment of OSA in adults, the strength of the evidence that MADs improve sleep apnea signs and symptoms was rated moderate.<sup>6</sup> More recently, 2 systematic reviews with meta-analysis have compared CPAP with oral devices for the management of OSA.<sup>19,20</sup> Pattipati et al (2022) identified literature comparing CPAP with MADs in mild to severe OSA.<sup>19</sup> 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 AASM and the American Academy of Dental Sleep Medicine.<sup>20</sup> The meta-analysis showed that oral appliances reduced the AHI, arousal index, and oxygen desaturation Index (ODI), 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 ODI, and in improving oxygen desaturation, supporting the use of CPAP as 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 versus custom-made MADs.<sup>21</sup> Twenty-five patients with mild-to-moderate OSA (mean AHI, 13.3 events/hour; range, 10.9 to 25 events/hour) were randomized to a 3-month trial of a ready-made or a custom-made device, with a 2-week washout between treatments. An overnight home sleep apnea test was performed at baseline and on the last night of the 3-month trial period. Patients used the custom-made device for more nights per week (7 vs. 3,  $p=.004$ ) and hours per night (5 vs. 3,  $p=.006$ ) than the ready-made device. Treatment response (AHI <5 events per hour) was obtained in 64% of patients during use of the custom-made device phase compared with a 24% response rate using the ready-made device ( $p<.001$ ). Treatment failure (<50% reduction in AHI) 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 was observed only during the custom-made device phase.

Another randomized crossover study by Bosschieter et al (2022) reported on results from a single-center study in patients with OSA.<sup>22</sup> Patients were randomized to either custom or noncustom MADs for 12 weeks. After the first 12 weeks of follow-up and a 1-week washout period, patients crossed over to the alternate treatment option. Of the 58 patients initially randomized, 40 patients completed the full follow-up. Investigators found that the median AHI significantly decreased from 16.3 events/hour (range, 7.7 to 24.8) to 10.7 events/hour (range, 5.6 to 16.6) with custom MADs ( $p=.010$ ) and from 16.3 events/hour to 7.8 events/hours (range, 2.9 to 16.1) with noncustom MADs ( $p<.001$ ). There were no significant differences found between the custom and noncustom MADs.

An RCT that randomized patients with OSA to either a ready-made MAD or custom-made MAD found similar effectiveness between groups in symptom control (Belkhode et al [2023]).<sup>23</sup> Twenty patients were randomized to each group and devices were worn for a duration of 3 months. At 1 and 3 months, AHI, oxygen saturation, Respiratory Disturbance Index (RDI), and ESS scores since baseline had all demonstrated significant improvements ( $p<.001$  for both groups in all outcomes). There were no significant differences between groups in outcome measures.

### Section 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 and 2022 meta-analysis demonstrated the efficacy of oral appliances for measures of OSA, but they were generally less effective than CPAP. Conflicting data exists on if custom-made MADs demonstrate superior impact on symptoms and QOL outcomes compared to ready-made MADs, based on available RCTs.

### Novel Obstructive Sleep Apnea Treatments

#### Clinical Context and Therapy Purpose

The purpose of novel OSA treatments in individuals who have OSA is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

#### *Populations*

The relevant population is individuals with OSA.

#### *Interventions*

The therapy being considered is novel OSA treatments (e.g., palate expansion, expiratory positive airway pressure [EPAP], oral pressure therapy).

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 gradually expand the upper and lower jaw and airway 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 and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. 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: CPAP or its variants. The major limitation of PAP therapy is poor patient 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 AHI, and subjective symptoms of sleepiness, typically measured with the ESS or the FOSQ. Additional health outcome measures relevant to OSA are summarized in Table 3 above.

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**

#### **Palate and Mandible Expansion**

##### **Case Series**

Singh et al (2016) reported on a series of 15 consecutive patients with severe sleep apnea who were treated with a DNA Appliance or mRNA Appliance.<sup>24</sup> All patients 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 of 45.9 events per hour to 16.5 ( $p < .01$ ) after a mean of 9.7 months of treatment.

Singh et al (2016) and Cress (2017) reported on a series of 19 patients who had mild-to-moderate OSA who were treated with a DNA or mRNA Appliance.<sup>25</sup> Only patients 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 ( $p<.001$ ) with the appliance, while the ODI improved from 6.3% to 2.6% ( $p<.001$ ). Limitations of these studies included the use of a home sleep apnea test rather than the more accurate laboratory polysomnography (PSG), uncertain blinding of the physician evaluating the sleep study, the small number of patients studied, lack of intention-to-treat (ITT) analysis, and lack of long-term follow-up.

### **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.

### **Nonrandomized Comparative Study**

Krakow et al (2008) reported on the use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP.<sup>26</sup> Patients had been referred by psychiatrists or primary care physicians for unspecified insomnia conditions, insomnia due to a mental disorder, or hypnotic dependence. Nearly all patients had anxiety, fear, and/or resistance regarding PAP therapy or the diagnosis of OSA. Thirty-nine patients 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 [EEG] leads); PAP therapy during 1 to 2 hours in bed in which the patient had the opportunity to fall asleep with the mask in place; and post-test follow-up. Thirty-five of 39 nap-tested patients 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 PAP-NAP 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 patients 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.<sup>27</sup> 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 patients 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 contacts with staff. The duration of use is unclear from the report, but at the time of follow-up 71% of patients who had initially refused PAP were considered users and 29% were non-users.

### **Nasal Expiratory Positive Airway Pressure Systematic Reviews**

A systematic review by Riaz et al (2015) identified 18 studies ( $N=920$ ) that had data on pre-and postnasal EPAP.<sup>28</sup> Study designs included 10 conference papers and 8 publications (case series, cohort studies, RCTs). For patients included in the meta-analysis ( $n=345$ ), AHI decreased from 27.32 to 12.78 events per hour ( $p<.001$ ). For 359 patients, ESS score modestly improved from 9.9 to 7.4 ( $p<.001$ ). Data from the Berry et al (2011) RCT (described below) 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.<sup>29</sup> Two hundred fifty patients 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. A PSG was performed on 2 nights (device-on, device-off, in 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 patients who had an AHI of 5 or more events per hour on the device-off PSG night. The oxygenation results (ODI) 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 patients in the EPAP group and by 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing due to adverse events. Overall, the validity of these results was limited by the high dropout rate and uncertainty of the clinical significance of the results. Furthermore, the trial did not report the racial/ethnic composition of enrolled patients and enrolled mostly men.

Kryger et al (2011), in an open-label extension of the randomized study by Berry et al (2011), evaluated the 12-month safety and durability of the treatment response in patients who had an initially favorable response to EPAP.<sup>30</sup> Included were 41 (32%) of the 127 patients 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 with the device-off PSG. Of the 51 (40%) of 127 eligible patients, 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 patients 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 patients, 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 patients might have responded to this device, and the patient compliance data might indicate a positive effect on daytime sleepiness that leads to continued use of the device in about 25% of patients. 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.<sup>31</sup> PSG with EPAP or a placebo device showed a significant mean improvement in Obstructive Apnea Index with EPAP (0.6 vs. 4.2, p=.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=.031) and Obstructive Sleep Apnea-18 questionnaire scores improved from 50 to 39 (p=.028). Other outcome measures did not improve significantly.

## Oral and OroNasal Pressure Therapy

### Randomized Controlled Trials

Lai et al (2019) reported a study with 22 patients with OSA who were incomplete responders to an oral appliance (AHI > 5).<sup>32</sup> 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. The trial did not report the racial/ethnic composition of enrolled patients and enrolled mostly men. Results demonstrated that 5 patients (23%) had at least a 50% reduction in total AHI with the oral EPAP compared to the oral appliance alone, while 10 patients (45%) had a 50% reduction in AHI with the combined oral and nasal EPAP valves. Neither of these was statistically significant. Only 2 patients (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.

### 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.<sup>33</sup> Patients with a body mass index (BMI) greater than 35 and AHI greater than 15 were excluded. For the 70 patients 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 [standard deviation (SD), 3.13] to 5.92 [SD, 2.83],  $p=.004$ ) and bed partners (7.35 [SD, 2.76] to 6.33 [SD, 2.80],  $p=.029$ ). In the 38 patients with mild OSA, AHI was reduced from 9.8 to 4.7 events/hour, 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 patients 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.<sup>34</sup> 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; 95% CI, 0.89 to 1.92;  $p<.001$ ) and bed partners (6.87 to 5.94; 95% CI, 0.15 to 1.68;  $p=.02$ ). The AHI was reduced from 6.85 to 5.01 ( $p<.001$ ), a difference that is not clinically significant.

## NightBalance Sleep Position Trainer

### Systematic Review

For some patients, 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 OSA.<sup>35</sup> 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 Food and Drug Administration (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. The 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.<sup>36</sup> Both devices reduced supine position by a median of 100% and reduced the median supine AHI to 0 events/hour during the 1-month sleep study. There were no significant differences between the groups for the ESS, VAS, and sleep-related QOL 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 patients 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.<sup>37</sup> 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 dropped out of the study by the 12-month follow-up due to adverse events or lack of efficacy, and the results in the publication represent only those individuals who remained in the study. Sensitivity analysis with ITT 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 ITT 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 patients (N=117) with exclusive positional OSA.<sup>38</sup> The investigators selected a non-inferiority margin of 5 events/hour for the AHI endpoint and 30 minutes for adherence. The sleep position trainer achieved non-inferiority with a difference of 3.58 events/hour. 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; p<.001). Patients 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 sleep apnea.

**Table 4. Summary of Key RCT Characteristics**

Study	Countries	Sites	Design	Participants	Interventions	
					Active	Comparator
Eijsvogel et al (2015) <sup>36</sup>	EU		Randomized parallel arm	55 patients with mild to moderate symptomatic	4 weeks with the first generation	4 weeks with commercially available inflated

Study	Countries	Sites	Design	Participants	Interventions	
				POSA who had been referred to a tertiary care center	NightBalance airbags on the back (n=26) Sleep Position Trainer (n=29)	
<b>de Ruiter et al (2018)<sup>37</sup></b>	EU	2	Randomized parallel arm	99 patients with mild to moderate POSA, defined as AHI > 2 times nonsupine AHI and total AHI < 15 events/hour	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)
<b>Berry et al (2019)<sup>38</sup>, (POSActive)</b>	US	11	Randomized crossover	117 treatment-naive patients with exclusive POSA, defined as a supine AHI > 2 times nonsupine AHI and a nonsupine AHI < 10 events/hour; total AHI was at least 15 events/hour (moderate to severe OSA)	6 weeks with the NightBalance Sleep Position Trainer	6 weeks with APAP

AHI: apnea/hypopnea index; APAP: auto-adjusting positive airway pressure; OAT: oral appliance therapy; OSA: obstructive sleep apnea; POSA: positional obstructive sleep apnea; RCT: randomized controlled trial.

**Table 5. Summary of Key RCT Results**

Study	AHI (SD)	Adherence (SD)	ESS (SD)	QOL (SD)
<b>Eijsvogel et al (2015)<sup>36</sup></b>		<i>Hours per Night (SD)</i>		<i>QSQ (SD)</i>
<b>N</b>	48	55	48	48
<b>NightBalance</b>	median 3.9 (min 0.4 to max 30.8)	median 6.5 (min 5.5 to max 7.2)	6.0 ± 3.6	5.4 ± 1.2
<b>TBT</b>	median 5.8 (min 0.2 to max 23.1)	median 4.5 (min 1.1 to max 7.0)	7.8 ± 4.3	4.8 ± 1.3
<b>p</b>		.078		
<b>de Ruiter et al (2018)<sup>37</sup></b>	<i>12 mo follow-up</i>	<i>Hours per Night (SD)</i>		<i>FOSQ (SD)</i>
<b>N</b>	58	57	46	30
<b>NightBalance</b>	7.1	5.2 (2.2)	7.0	19.0
<b>OAT</b>	5.0	5.0 (2.0)	4.0	17.7
<b>p</b>	.792	.743	.073	.864
<b>Berry et al (2019)<sup>38</sup>, (POSActive)</b>		<i>Minutes per Night</i>		
<b>NightBalance</b>	7.29 (6.8)	345.3 (111.22)	8.27 (4.98)	17.32 (2.18)
<b>CPAP</b>	3.71 (5.1)	286.98 (128.9)	7.37 (3.98)	17.62 (1.87)
<b>p</b>	<.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; QOL: quality of life; QSQ: Quebec Sleep Questionnaire; RCT: randomized controlled trial; SD: standard deviation; TBT: tennis ball technique (airbags).

**Table 6. Study Relevance Limitations**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-up <sup>e</sup>
<b>Eijsvogel et al (2015)<sup>36</sup></b>	3, 5. Not all patients would have qualified for treatment. The mean score on the Epworth Sleepiness Score was < 10. 5. Racial/ethnic diversity of enrolled patients is not reported.	4. This was a first generation device.			1. There was no long-term follow-up after the 4 week intervention.
<b>de Ruiter et al (2018)<sup>37</sup></b>	5. Racial/ethnic diversity of enrolled patients is not reported.				
<b>Berry et al (2019)<sup>38</sup>. (POSAtive)</b>	5. Racial/ethnic diversity of enrolled patients is not reported.				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.

<sup>a</sup> Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

<sup>b</sup> Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

<sup>c</sup> Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

<sup>d</sup> 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.

<sup>e</sup> Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 7. Study Design and Conduct Limitations**

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Data Completeness <sup>d</sup>	Power <sup>e</sup> Statistical <sup>f</sup>
<b>Eijsvogel et al (2015)<sup>36</sup></b>	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	
<b>de Ruiter et al (2018)<sup>37</sup></b>	3. Allocation concealment unclear	1, 2. Participants could not be blinded to treatment assignment.	2. Patients lost to follow-up were not counted as treatment failures in the primary analysis.	1, 2. High loss to follow-up; 59% of patients completed the study.	
<b>Berry et al (2019)<sup>38</sup>. (POSAtive)</b>	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.

<sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

<sup>b</sup> Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

<sup>c</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

<sup>d</sup> 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).

<sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

<sup>f</sup> 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 patient; 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 patients with mild to moderate positional OSA.<sup>39</sup> There were 145 patients 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 patients, 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. Objective Sleep Position Trainer compliance, defined as more than 4 hours of usage per night as an average over 168 nights, was 64.4%; regular use, defined as at least 4 hours per 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 patients at the start of the study to less than 60 by 6 months. It is uncertain whether the number of patients using the device would be as high as this outside of a trial.

Beyers et al (2018) invited patients to participate in a 1-month trial of the sleep position trainer as part of a standard clinical pathway at a university hospital.<sup>40</sup> In order to qualify for the trial, patients were required to have an overall AHI of > 5 events/hour, 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 patients, 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 patients (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 patients 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 patients with positional OSA who had a 1-month trial of the NightBalance device.<sup>41</sup> About half of patients (n=27) were considered adherent during the trial, and half of those (n=13) wanted to purchase the device. Ten patients had a higher response to the vibrations and were considered cured.

### Section Summary: Novel Obstructive Sleep Apnea Treatments

The evidence on palate and mandible expansion devices includes a few small case series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on the PAP-NAP includes 1 comparative trial with historical controls and a retrospective cohort study of patients 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 patient 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. The evidence on nasal EPAP devices in patients 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 scores. An oral EPAP device did not have significant benefit when added to an oral appliance in a small RCT.



No controlled trials on eXciteOSA were identified. The evidence includes 2 prospective, single-arm studies in patients with primary snoring or mild OSA. The available evidence suggests that when used for 20 min per 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 patients with mild OSA, the improvement in AHI in these uncontrolled trials remained modest. With a mean ESS of less than 10, this group of patients might not be considered symptomatic. Controlled studies are needed to evaluate whether patients who meet the criteria for treatable OSA improve and whether individuals would continue use after the 6-week trial period. 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 PAP in patients 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 patients used the sleep position trainer for more than 4 hours per night, but another observational study found that only about one-quarter of patients 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.

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

### **2009 Input**

In response to requests, input was received from 5 physician specialty societies (6 reviewers) and 3 academic medical centers while this policy was under review in 2009. Professional society guidelines and position statements were also reviewed. In general, input supported the use of polysomnography (PSG), portable sleep monitoring tests, multiple sleep latency tests, and continuous positive airway pressure (CPAP) for adults as described in the policy. The update included reviewers' 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 Otolaryngology-Head and Neck Surgery**

In 2021, the American Academy of Otolaryngology-Head and Neck Surgery updated its position statement on the treatment of OSA.<sup>42</sup> The academy states that adenotonsillectomy is the first line

treatment in pediatric OSA. In most adults, CPAP is the first-line treatment. Surgical procedures may be considered when positive airway pressure (PAP) therapy is inadequate.

### 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 the AAP's 2002 guidelines.<sup>43,44</sup> 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 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.<sup>45</sup> The levels of recommendation are "standard" (generally accepted patient-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 PAP:

- CPAP is indicated for patients with moderate to severe OSA (Standard) and mild OSA (Option).
- Bilevel PAP can be considered in CPAP-intolerant patients (Consensus).
- Autotitrating positive airway pressure (APAP) can be considered in CPAP-intolerant patients (Consensus).

Treatment with oral appliances (OA) is indicated for "patients 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 (2019) also published a clinical practice guideline on the treatment of OSA with PAP that was based on a systematic review of the evidence.<sup>4,5</sup> "A STRONG (i.e., "We recommend...") recommendation is one that clinicians should follow under most circumstances. A CONDITIONAL recommendation (i.e., "We suggest...") reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients."

The AASM provided strong recommendations for the following use of PAP therapy in adults:

- Use of PAP to treat OSA in adults with excessive sleepiness.
- That PAP therapy be initiated at home using APAP or in-laboratory PAP titration in adults with no significant morbidities.
- Use of CPAP or APAP for ongoing treatment of OSA.
- That clinicians provide educational interventions with the initiation of PAP.

The AASM provided conditional recommendations (suggest) for the following use of PAP therapy in adults:

- Use of PAP to treat OSA in adults with impaired sleep-related quality of life (QOL).
- Use of PAP to treat OSA in adults with comorbid hypertension.
- Use CPAP or APAP over Bilevel PAP in the routine treatment of OSA.

- That behavioral and/or troubleshooting interventions be given during the initial period of PAP therapy.
- That clinicians use telemonitoring during the initial period of PAP therapy.

The AASM and the American Academy of Dental Sleep Medicine (2015) published guidelines on the treatment of OSA and snoring with OA therapy.<sup>20</sup> The 2 societies provided a recommendation of "standard" that sleep physicians consider prescription of OA, 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 noncustom 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 Heart Association**

In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease.<sup>46</sup> The treatment options for OSA and eligibility for their use are described in the statement and briefly summarized below:

- CPAP: "The Centers for Medicare & Medicaid Services cover CPAP on the basis of an AHI [apnea/hypopnea index] or REI [respiratory event index]  $\geq 15$  events per hour or AHI (or REI)  $\geq 5$  with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented comorbidities (i.e., hypertension, ischemic heart disease, or history of stroke)."
- APAP: "Same as CPAP."
- Bilevel PAP: "Patients intolerant of CPAP pressure or who require additional ventilatory support."
- 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 patients who do not tolerate CPAP."

The statement also notes the following with regards to treatment:

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

### **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).<sup>47</sup> 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 Thoracic Society**

The American Thoracic Society (2016) published a research statement on the long-term effects and treatment of mild OSA in adults.<sup>48</sup> The Society's systematic review concluded:

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

**National Institute for Health and Care Excellence**

NICE provides guidance on medical management in individuals with varying degrees of OSA.<sup>49</sup> They recommend offering fixed-level CPAP in those with mild OSA when symptoms affect QOL and usual daytime activities if lifestyle changes alone have been unsuccessful or are considered inappropriate. They recommend APAP as an alternative to fixed-level CPAP in those unable to tolerate CPAP. In individuals who cannot tolerate or refuse CPAP, they recommend offering a customized mandibular advancement device. In individuals with moderate to severe OSA, CPAP is recommended as a treatment option, with APAP offered as an alternative in those unable to tolerate CPAP. Similarly, a customized mandibular advancement device may be used if an individual refuses PAP or is unable to tolerate PAP. NICE also states that a positional modifier may be considered for those with mild to moderate positional OSA if other treatments are unsuitable or not tolerated, but this should not be a first-line treatment option.

**U.S. Preventive Services Task Force Recommendations**

None.

**Medicare National Coverage**

In 2001, the Centers for Medicare & Medicaid Services published a decision memorandum on CPAP that addressed how to define moderate-to-severe OSA as a guide to a coverage policy for CPAP. This review of the literature suggested there is a risk of hypertension with an AHI greater than 15 events per hour, and thus treatment would be warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 events per hour and associated symptoms, CMS concluded that the data from 3 randomized controlled trials demonstrated improved daytime somnolence and functioning in those treated with CPAP.

In 2008, CMS expanded coverage of CPAP to include those beneficiaries with a diagnosis of OSA made with a combination of clinical evaluation and unattended home sleep monitoring using a device with at least 3 channels.<sup>50,51</sup> There is variability in the published medical literature about the definition of the events that constitute a respiratory disturbance, and, for the purposes of this national coverage decision, a respiratory disturbance was defined in the context of the sleep test technology of interest and, for portable monitoring devices that do not measure AHI or Respiratory Disturbance Index (RDI) directly, does not require direct measurement of airflow.

Effective in March 2008, CMS determined that CPAP therapy, when used in adults with OSA, would be considered reasonable and necessary in the following situations:

1. "The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.

2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example, a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.
3. A positive diagnosis of OSA for the coverage of CPAP must include clinical evaluation and a positive:
  1. attended PSG performed in a sleep laboratory; or
  2. unattended HST [home sleep test] with a Type II home sleep monitoring device; or
  3. unattended HST with a Type III home sleep monitoring device; or
  4. unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels.
4. The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision.
5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criteria using the AHI or RDI are met:
  1. AHI or RDI greater than or equal to 15 events per hour, or
  2. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.
6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at minimum the number of events that would have been required in a 2-hour period.
7. Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline and with at least a 4% oxygen desaturation.
8. Coverage with Evidence Development (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address 1 or more of the following questions:
  1. In Medicare aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Types II, III & IV HST in identifying subjects with OSA who will respond to CPAP?
  2. In Medicare aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Types II, III & IV HST, does CPAP cause clinically meaningful harm?"

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in May 2023 identified over 200 ongoing studies on the medical management of OSA.

**Appendix 1**

**Obstructive Sleep Apnea Oral Appliance Therapy Check-off List:**

Date of pre-authorization request: \_\_\_\_\_

Name of patient: \_\_\_\_\_

Blue Shield of California number: \_\_\_\_\_

The following are a summary of my clinical findings:

- |                                                                                                         |                              |
|---------------------------------------------------------------------------------------------------------|------------------------------|
| 1. AHI = 15+:                                                                                           | Yes _____ No _____           |
| 2. RDI = 15+:                                                                                           | Yes _____ No _____ N/A _____ |
| 3. ESS = 10+:                                                                                           | Yes _____ No _____ N/A _____ |
| 4. AHI or RDI <15 but >=5 with hypertension or ESS >10:                                                 | Yes: _____ No: _____         |
| 5. Evidence of periodontal disorder:                                                                    | Yes: _____ No: _____         |
| 6. Evidence of temporomandibular disorder:                                                              | Yes: _____ No: _____         |
| 7. Oral appliance is custom-made device by DDS:                                                         | Yes _____ No _____           |
| 8. Physician prescription for oral device is attached:                                                  | Yes _____ No _____           |
| 9. Acceptable Sleep study attached (less than 5 years old):                                             | Yes _____ No _____           |
| 10. CPAP intolerance (Affidavit) form or statement indicating the patient refuses to use CPAP attached: | Yes _____ No _____           |
| 11. Patient undergoing orthodontic therapy:                                                             | Yes _____ No _____           |

Explanation/Comments

-----  
 -----  
 -----

I hereby certify the information above is true and accurate to the best of my clinical knowledge at the time of my clinical examination:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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## Documentation for Clinical Review

### CPAP and APAP

#### Please provide the following documentation:

- History and physical and/or consultation notes including documentation of sleep apnea including:
  - Symptoms
  - Comorbidities
- Prior Polysomnography or Sleep study reports including AHI/RDI/REI
- Prior treatment and response (including documented failed trial of CPAP; if applicable)
- Current treatment plan
- Completed sleep questionnaires (e.g., Epworth Sleepiness Scale, Berlin Questionnaire, STOP-Bang) if applicable
- Completed and signed OSA Oral Appliance Therapy Check-off List by the provider if applicable
- Sleep specialty provider recommendation and prescription for positive airway pressure device or intraoral appliance; if applicable
- If request is for CPAP replacement, please indicate reason
- Name and type of device used for home sleep study if applicable

### Intraoral Appliances

#### Please provide the following documentation:

- History and physical and/or consultation notes including documentation of sleep apnea including:
  - Symptoms

- Comorbidities
- Prior Polysomnography or Sleep study reports including AHI/RDI/REI
- Prior treatment and response (including documented failed trial of CPAP; if applicable)
- Current treatment plan
- Completed sleep questionnaires (e.g., Epworth Sleepiness Scale, Berlin Questionnaire, STOP-Bang) if applicable
- Completed and signed OSA Oral Appliance Therapy Check-off List by the provider if applicable
- Sleep specialty provider recommendation and prescription for positive airway pressure device or intraoral appliance; if applicable
- If request is for CPAP replacement, please indicate reason
- Name and type of device used for home sleep study if applicable

**Post Service (in addition to the above, please include the following):**

- Polysomnography or Home Sleep study reports

**Coding**

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT <sup>®</sup>	None	
HCPCS	A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each
	A7028	Oral cushion for combination oral/nasal mask, replacement only, each
	A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair
	A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
	A7035	Headgear used with positive airway pressure device
	A7036	Chinstrap used with positive airway pressure device
	A7037	Tubing used with positive airway pressure device
	A7038	Filter, disposable, used with positive airway pressure device
	A7039	Filter, nondisposable, used with positive airway pressure device
	A7049	Expiratory positive airway pressure intranasal resistance valve <b>(Code effective 4/1/2023)</b>
	E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
	E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

Type	Code	Description
	E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
	E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
	E0490	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote <b>(Code effective 10/1/2023)</b>
	E0491	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply <b>(Code effective 10/1/2023)</b>
	E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application <b>(Code effective 1/1/2024)</b>
	E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply <b>(Code effective 1/1/2024)</b>
	E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type <b>(Code effective 1/1/2024)</b>
	E0561	Humidifier, nonheated, used with positive airway pressure device
	E0562	Humidifier, heated, used with positive airway pressure device
	E0601	Continuous positive airway pressure (CPAP) device
	K1001	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type <b>(Deleted code effective 1/1/2024)</b>
	K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
	K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application <b>(Deleted code effective 1/1/2024)</b>
	K1029	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply <b>(Deleted code effective 1/1/2024)</b>

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
10/01/2022	New policy. Split from policy 2.01.18
06/01/2023	Coding update.
08/01/2023	Annual review. No change to policy statement. Literature review updated.
12/01/2023	Coding update.
03/01/2024	Coding update.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p><b>Medical Management of Obstructive Sleep Apnea Syndrome 8.01.67</b></p> <p><b>Policy Statement:</b>  <b>Medical Management</b></p> <ol style="list-style-type: none"> <li>I. Continued positive airway pressure (<a href="#">CPAP</a>) (or Auto-adjusting positive airway pressure [APAP]) may be considered <b>medically necessary</b> in adult or pediatric individuals with <a href="#">clinically significant obstructive sleep apnea (OSA)</a>, provided that diagnosis was based on the performance of an <a href="#">approved</a> diagnostic study.</li> <li>II. Bilevel positive airway pressure (BiPAP) may be considered <b>medically necessary</b> with <b>both</b> of the following:                     <ol style="list-style-type: none"> <li>A. Individual has <a href="#">clinically significant OSA</a></li> <li>B. Individual failed a prior trial of CPAP or whom BiPAP is found to be more effective in the <a href="#">sleep lab</a></li> </ol> </li> <li>III. <a href="#">Replacement of a PAP device</a> after the warranty period (usually 2-5 years) may be considered <b>medically necessary</b> with <b>all</b> of the following:                     <ol style="list-style-type: none"> <li>A. Documentation that the device is no longer functioning properly</li> <li>B. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</li> <li>C. Documentation of current compliance prior to the problem with the machine</li> <li>D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</li> <li>E. Documentation the device is out of warranty</li> </ol> </li> <li>IV. <a href="#">Replacement of a PAP device</a> within the warranty period may be considered <b>medically necessary</b> with <b>all</b> of the following:</li> </ol>	<p><b>Medical Management of Obstructive Sleep Apnea Syndrome 8.01.67</b></p> <p><b>Policy Statement:</b>  <b>Medical Management</b></p> <ol style="list-style-type: none"> <li>I. Continued positive airway pressure (<a href="#">CPAP</a>) (or Auto-adjusting positive airway pressure [APAP]) may be considered <b>medically necessary</b> in adult or pediatric individuals with <a href="#">clinically significant obstructive sleep apnea (OSA)</a>, provided that diagnosis was based on the performance of an <a href="#">approved</a> diagnostic study.</li> <li>II. Bilevel positive airway pressure (BiPAP) may be considered <b>medically necessary</b> with <b>both</b> of the following:                     <ol style="list-style-type: none"> <li>A. Individual has <a href="#">clinically significant OSA</a></li> <li>B. Individual failed a prior trial of CPAP or whom BiPAP is found to be more effective in the <a href="#">sleep lab</a></li> </ol> </li> <li>III. <a href="#">Replacement of a PAP device</a> after the warranty period (usually 2-5 years) may be considered <b>medically necessary</b> with <b>all</b> of the following:                     <ol style="list-style-type: none"> <li>A. Documentation that the device is no longer functioning properly</li> <li>B. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</li> <li>C. Documentation of current compliance prior to the problem with the machine</li> <li>D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</li> <li>E. Documentation the device is out of warranty</li> </ol> </li> <li>IV. <a href="#">Replacement of a PAP device</a> within the warranty period may be considered <b>medically necessary</b> with <b>all</b> of the following:</li> </ol>

POLICY STATEMENT

(No changes)

BEFORE	AFTER
<p>A. Documentation that the device is no longer functioning properly</p> <p>B. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> <p>C. Documentation of current compliance prior to the problem with the machine</p> <p>D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</p> <p>E. Documentation that the cost of repairs would exceed that of replacement</p> <p>V. A single oral appliance (tongue-retaining devices or mandibular advancing/positioning devices) may be considered <b>medically necessary</b> in adults with <a href="#">clinically significant OSA</a> when <b>all</b> of the following conditions have been met:</p> <p>A. Initial or continued use of CPAP is <a href="#">clinically not tolerated or is refused by the patient</a></p> <p>B. The device is prescribed by a treating provider</p> <p>C. The device is custom-fitted by qualified dental personnel</p> <p>D. There is documentation of absence of temporomandibular dysfunction or periodontal disease</p> <p>E. Provider has reviewed, completed and signed an <a href="#">OSA Oral Appliance Therapy Check-off List</a> (signed copy attached to request in addition to appropriate medical record documentation supporting the check list)</p> <p>VI. <a href="#">Replacement of an oral appliance</a> (OA) <i>after</i> the warranty period (usually 3 years) may be considered <b>medically necessary</b> with <b>all</b> of the following:</p> <p>A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate</p> <p>B. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p>	<p>A. Documentation that the device is no longer functioning properly</p> <p>B. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> <p>C. Documentation of current compliance prior to the problem with the machine</p> <p>D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</p> <p>E. Documentation that the cost of repairs would exceed that of replacement</p> <p>V. A single oral appliance (tongue-retaining devices or mandibular advancing/positioning devices) may be considered <b>medically necessary</b> in adults with <a href="#">clinically significant OSA</a> when <b>all</b> of the following conditions have been met:</p> <p>A. Initial or continued use of CPAP is <a href="#">clinically not tolerated or is refused by the patient</a></p> <p>B. The device is prescribed by a treating provider</p> <p>C. The device is custom-fitted by qualified dental personnel</p> <p>D. There is documentation of absence of temporomandibular dysfunction or periodontal disease</p> <p>E. Provider has reviewed, completed and signed an <a href="#">OSA Oral Appliance Therapy Check-off List</a> (signed copy attached to request in addition to appropriate medical record documentation supporting the check list)</p> <p>VI. <a href="#">Replacement of an oral appliance</a> (OA) <i>after</i> the warranty period (usually 3 years) may be considered <b>medically necessary</b> with <b>all</b> of the following:</p> <p>A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate</p> <p>B. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p>

## POLICY STATEMENT

(No changes)

BEFORE	AFTER
<ul style="list-style-type: none"> <li>C. Documentation of current compliance prior to the problem with the OA</li> <li>D. Documentation of benefit from the use of the OA (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</li> <li>E. Provider has reviewed, completed and signed an <a href="#">OSA Oral Appliance Therapy Check-off List</a> (signed copy attached to request)</li> </ul>	<ul style="list-style-type: none"> <li>C. Documentation of current compliance prior to the problem with the OA</li> <li>D. Documentation of benefit from the use of the OA (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</li> <li>E. Provider has reviewed, completed and signed an <a href="#">OSA Oral Appliance Therapy Check-off List</a> (signed copy attached to request)</li> </ul>
<p>VII. <a href="#">Replacement of an oral appliance</a> (OA) <i>within</i> the warranty period may be considered <b>medically necessary</b> with <b>all</b> of the following:</p> <ul style="list-style-type: none"> <li>A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate</li> <li>B. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</li> <li>C. Documentation of current compliance prior to the problem with the OA</li> <li>D. Documentation of benefit from the use of the OA</li> <li>E. Documentation that the cost of repairs would exceed that of replacement</li> <li>F. Provider has reviewed, completed and signed an <a href="#">OSA Oral Appliance Therapy Check-off List</a> (signed copy attached to request)</li> </ul>	<p>VII. <a href="#">Replacement of an oral appliance</a> (OA) <i>within</i> the warranty period may be considered <b>medically necessary</b> with <b>all</b> of the following:</p> <ul style="list-style-type: none"> <li>A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate</li> <li>B. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</li> <li>C. Documentation of current compliance prior to the problem with the OA</li> <li>D. Documentation of benefit from the use of the OA</li> <li>E. Documentation that the cost of repairs would exceed that of replacement</li> <li>F. Provider has reviewed, completed and signed an <a href="#">OSA Oral Appliance Therapy Check-off List</a> (signed copy attached to request)</li> </ul>
<p>VIII. <a href="#">Replacement of an oral appliance</a> due to changes in dental alignment may be considered <b>medically necessary</b> with <b>all</b> of the following:</p> <ul style="list-style-type: none"> <li>A. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</li> <li>B. Provider has reviewed, completed and signed an <a href="#">OSA Oral Appliance Therapy Check-off List</a> (signed copy attached to request)</li> <li>C. Initial or continued use of CPAP is not tolerated or is refused by the patient</li> </ul>	<p>VIII. <a href="#">Replacement of an oral appliance</a> due to changes in dental alignment may be considered <b>medically necessary</b> with <b>all</b> of the following:</p> <ul style="list-style-type: none"> <li>A. Documentation of <a href="#">clinically significant OSA</a> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</li> <li>B. Provider has reviewed, completed and signed an <a href="#">OSA Oral Appliance Therapy Check-off List</a> (signed copy attached to request)</li> <li>C. Initial or continued use of CPAP is not tolerated or is refused by the patient</li> </ul>



POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>D. The device is prescribed by a treating provider</p> <p>E. The device is custom fitted by qualified dental personnel</p> <p>F. There is documentation of absence of significant temporomandibular dysfunction and periodontal disease</p> <p>G. Needed after completion of orthodontic treatment that was prescribed and supervised by an orthodontist</p> <p>IX. The following are considered <b>investigational</b>:</p> <p>A. Nasal expiratory positive airway pressure (EPAP)</p> <p>B. Oral pressure therapy devices</p> <p>C. Mandibular/palatal expansion devices for the treatment of OSA</p> <p>D. The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP)</p> <p>E. The use of a sleep positioning trainer with vibration</p> <p>F. The use of daytime electrical stimulation of the tongue</p> <p>G. The use of CPAP, bi-level positive airway pressure, APAP, ASV and intraoral appliances that do not meet the above criteria for the treatment of OSA</p> <p>H. Mandibular repositioning (daytime), bruxism and anti-snoring oral appliances for the treatment of OSA</p>	<p>D. The device is prescribed by a treating provider</p> <p>E. The device is custom fitted by qualified dental personnel</p> <p>F. There is documentation of absence of significant temporomandibular dysfunction and periodontal disease</p> <p>G. Needed after completion of orthodontic treatment that was prescribed and supervised by an orthodontist</p> <p>IX. The following are considered <b>investigational</b>:</p> <p>A. Nasal expiratory positive airway pressure (EPAP)</p> <p>B. Oral pressure therapy devices</p> <p>C. Mandibular/palatal expansion devices for the treatment of OSA</p> <p>D. The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP)</p> <p>E. The use of a sleep positioning trainer with vibration</p> <p>F. The use of daytime electrical stimulation of the tongue</p> <p>G. The use of CPAP, bi-level positive airway pressure, APAP, ASV and intraoral appliances that do not meet the above criteria for the treatment of OSA</p> <p>H. Mandibular repositioning (daytime), bruxism and anti-snoring oral appliances for the treatment of OSA</p>