
Medical Policy



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. When Centers for Medicare and Medicaid (CMS) coverage rules are not fully developed, this medical policy may be used by BCBSM or BCN Medicare Advantage plans 42 CFR § 422.101 (b)(6). Please refer to the appropriate certificate or contract for benefit information. This policy may be updated and is therefore subject to change.

***Current Policy Effective Date: 1/1/26**
(See policy history boxes for previous effective dates)

Title: Obstructive Sleep Apnea – Non-surgical Treatment

Description

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. 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 but are not limited to nasal expiratory positive airway pressure (EPAP), palate and mandible expansion, oral pressure therapy, and sleep position training devices.

Medical Policy Statement

Positive pressure airway devices for the treatment of obstructive sleep apnea are **established** when criteria are met.

Oral appliances for the treatment of OSA are **established** when criteria are met.

Palate and mandible expansion devices for the treatment of OSA are considered **experimental/investigational**. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Nasal Expiratory Positive Airway Pressure (nasal EPAP) for the treatment of OSA is considered **experimental/investigational**. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Oral pressure therapy for the treatment of OSA is considered **experimental/investigational**. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

The use of sleep position training devices for the treatment of positional OSA are considered **experimental/investigational**. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered **experimental/investigational**. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

The use of neuromuscular electrical stimulation of the tongue for the treatment of OSA is considered **experimental/investigational**. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

INCLUSIONS:

Auto-adjusting positive airway pressure (APAP) for the titration of pressure in individuals with clinically significant OSA defined as those who have:

- An AHI, RDI, or Respiratory Event Index (REI) of at least 15 events per hour, **OR**
- An AHI, RDI, or REI of at least 5 events per hour in an individual with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke); **OR**
- If there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued. 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.

Continuous Positive Airway Pressure (CPAP) in adult or pediatric individuals with clinically significant OSA.

- Clinically significant OSA in adults is:
 - An AHI, RDI, or REI ≥ 15 , **OR**
 - An AHI, RDI, or REI ≥ 5 in an individual with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).
- Clinically significant OSA in pediatric individuals is:
 - An AHI or RDI ≥ 5 **OR**
 - An AHI or RDI ≥ 1.5 in an individual with excessive daytime sleepiness, behavioral problems or hyperactivity.

Bilevel positive airway pressure (BiPAP) or APAP in both pediatric and adult individuals with clinically significant OSA who have failed a prior trial of CPAP or for whom bilevel positive airway pressure is found to be more effective in the sleep lab.

Oral Appliances (Tongue-retaining devices or mandibular advancing/positioning devices) in adults with clinically significant OSA when the following criteria are met (Verify coverage of oral appliances under the DME benefit):

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

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

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

Note: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for individuals with severe OSA, because oral appliances have been shown to be less efficacious in individuals with severe OSA than in individuals with mild-to-moderate OSA. Therefore, it is particularly important that individuals 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.

Definition of an Oral Appliance for OSA⁵⁴

- A custom-fabricated appliance, using digital or physical impressions and models of an individual's oral structures and physical needs
- Oral appliances must be custom made but it may include a prefabricated component in the final appliance. The device may not be primarily prefabricated.
- Includes all appliances, including titration appliances
- Made of biocompatible materials
- Engages the maxillary and mandibular arches/must have good retention to the dentition and prevent dislodging
- Includes a mechanism that advances the mandible in increments of 1 mm or less with a protrusive adjustment range of at least 5 mm. This mechanism may or may not include fixed mechanical hinges or metallic materials.
- Reversal of the advancement is possible
- The protrusive setting must be verifiable⁵⁴

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

EXCLUSIONS:

- Diagnosis of snoring without sleep apnea.
- Use of CPAP, BiPAP, APAP, and oral appliances for the treatment of OSA when the above criteria are not met.
- Prefabricated (not custom-fit) devices (e.g., sport mouth guards, mouth guards which can be purchased in a retail store or pharmacy).
- Screening tests (e.g., questionnaire, pulse oximetry, rhinometry, and laryngometry, etc.) performed by a dentist.
- Use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP).
- Use of neuromuscular electrical stimulation of the tongue.
- Palate and mandible expansion devices for the treatment of OSA.
- Nasal Expiratory Positive Airway Pressure and oral pressure therapy devices.
- Use of sleep positioning trainers including those with vibration (e.g., NightBalance Lunoa SPT system) for the treatment of positional OSA.

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

Established codes:

A7030	A7031	A7032	A7033	A7034	A7035
A7036	A7037	A7038	A7039	A7046	E0470
E0471	E0472	E0486	E0561	E0562	E0601

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

A7047	A7049	E0485	E0492	E0493	E0530
E1399					

Background

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 individuals how likely they are to fall asleep in different scenarios such as watching TV, sitting quietly in a car, or sitting and talking to someone. Daytime sleepiness is uncommon in young children with OSA. Symptoms in children may include disturbed sleep and daytime neurobehavioral problems. In otherwise healthy children, OSA is usually associated with adenotonsillar hypertrophy and/or obesity.

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

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

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

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

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

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

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

Diagnosis

Obstructive sleep apnea is widely underdiagnosed with up to 95% of individuals with clinically significant OSA reporting no prior OSA diagnosis. Moreover, underdiagnosis is particularly prevalent in Black individuals. The criterion standard diagnostic test for sleep disorders is a polysomnogram performed in a sleep laboratory.² A standard polysomnogram includes EEG, submental electromyogram (EMG) and electrooculogram (to detect rapid eye movement [REM])

sleep) for sleep staging. Polysomnography (PSG) also typically includes electrocardiography and monitoring of respiratory airflow and effort, snoring, oxygen desaturation, and sleep position. An attended study ensures that the electrodes and sensors are functioning adequately and do not dislodge during the night. In addition, an attendant is able to identify severe OSA in the first part of the night and titrate continuous positive airway pressure (CPAP) in the second part of the night, commonly known as a "split-night" study. If successful, this strategy eliminates the need for an additional PSG for CPAP titration. Definitions of terms and scoring criteria for OSA are presented in Table 1.

Table 1. Definitions of Terms and Scoring Criteria for OSA

Terms	Definition
Respiratory event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 3 or 4% decrease in arterial oxygen desaturation (depending on the scoring criteria) or an arousal. Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or associated arousal.
RERA	Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea
Respiratory event reporting	
AHI	The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available.
OSA	Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
Mild OSA	In adults: AHI or RDI of 5 to <15. In children: AHI $\geq$ 1 to <5
Moderate OSA	AHI or RDI of 15 to <30; Children: AHI of $\geq$ 5 to <10
Severe OSA	Adults: AHI or RDI $\geq$ 30; Children: AHI of $\geq$ 10
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.
Positive airway pressure	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP
PAP	Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure.
PAP failure	Usually defined as an AHI greater than or equal to 15 events per hour while using CPAP
PAP intolerance	CPAP use for <4 hours per night for $\geq$ 5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in individuals with mild, moderate, or severe OSA

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

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.

Treatment

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances and the use of various types of positive airway pressure (PAP) therapy (i.e., fixed CPAP, bilevel positive airway pressure, or auto-adjusting positive airway pressure) during sleep. Treatment with a positive pressure airway device is a highly effective treatment for obstructive sleep apnea. For some individuals, improvement in the quality of sleep and the quality of life are noticeable after a single night's use.

The positive airway pressure device consists of three main components, the flow generator that supplies the airflow, the interface or the nasal/face mask, nasal pillow or lip seal mouthpiece and the hose that connects the flow generator to the interface. Positive airway pressure devices have additional optional features that can improve comfort and usage compliance. Some of those features include heated or non-heated humidity, exhalation pressure relief, and a ramp feature that allows the device to gradually rise to the prescribed level of pressure, flexible chinstraps, data logging, automatic altitude adjustment and DC power source versus AC power source.

The various positive airway pressure devices work differently and have certain advantages as illustrated in Table 2 below.

Table 2. Types of Positive Pressure Devices

Positive Pressure Device	How it works	Advantages
CPAP (Continuous Positive Airway Pressure)	- Continuous positive airway pressure (CPAP) has become the first line of treatment for: OSA, some forms of CSA - Works by creating a "pneumatic splint" for the upper airway, preventing the soft tissues of the upper airway from narrowing and collapsing Pressurized air is sent from a flow generator through air tubing and a mask to the face - through to the upper airway	- Improvement in the quality of sleep - Improvement in the quality of life Patient's sleep partner also benefits from markedly improved sleep quality, due to the amelioration of the patient's loud snoring
APAP (Auto-adjusting positive airway pressure)	- An intelligent therapeutic device that automatically titrates the amount of pressure delivered to the patient in response to airway events such as: - Apneas - Hypopneas - Flow limitation - Snoring - Delivers mean pressures below that of a CPAP device; generating only the pressure that is necessary at any given time - Decreases pressure between event-laden periods May be particularly suited to patients with: REM-related apnea, positional apnea, non-compliant with standard CPAP therapy	Resistance is measured in the patient's breathing delivering the precise pressure required at a given moment avoiding the compromise of fixed pressure delivery system such as CPAP
BiPAP (Bilevel Positive Airway Pressure)	- Designed specifically to treat a broad range of conditions, including some that require 24-hour ventilator support including both CSA, OSA or a combination of both - Adapts to the patient's ventilatory needs on a breath-by-breath basis	- Treats complex sleep apnea syndrome and CSA - Delivers two levels of air pressure that are set to coincide with the patient's

- | | |
|---|---|
| <ul style="list-style-type: none"> Automatically calculates a target ventilation (90% of the patient's recent average ventilation) Automatically adjusts the pressure support | <ul style="list-style-type: none"> inspiratory and expiratory efforts Normalizes breathing, completely suppressing CSA and/or Cheyne-Stokes respiration Improves sleep architecture (the amount of time the patient spends in slow-wave and REM sleep increases) <p>Enhances quality of life for patients with CSA</p> |
|---|---|

A number of other treatments for OSA are available and include oral appliances, neuromuscular electric tongue stimulation (e.g., ExciteOSA), and novel devices including nasal expiratory positive airway pressure (EPAP), palate and mandible expansion, oral pressure therapy, and sleep position training devices.

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

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

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

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

The general outcomes of interest for the treatment of OSA are the number of apneas or hypopneas during sleep, measured by the Apnea/Hypopnea Index (AHI), and subjective symptoms of sleepiness, typically measured with the Epworth Sleepiness Scale (ESS) or the

Functional Outcomes of Sleep Questionnaire (FOSQ). Additional health outcome measures relevant to OSA are summarized in Table 3.

Table 3. Health Outcome Measures Relevant to OSA

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

AHI: apnea/hypopnea Index; ESS: Epworth Sleepiness

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

Summary of Evidence

For individuals who have obstructive sleep apnea (OSA) who receive positive airway pressure (PAP) devices, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and a cohort study. Relevant outcomes are symptoms, functional outcomes, and quality of life (QOL). Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous PAP (CPAP) during sleep. A diagnostic sleep study may be followed by a trial of APAP to evaluate efficacy and adjust pressure. Studies have suggested that both CPAP and APAP are associated with improvements in sleep architecture. Additionally, 11-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. If the patient is intolerant of CPAP, APAP or bilevel PAP may also be indicated. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who use oral appliances, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. Oral appliances 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 oral devices demonstrate superior impact on symptoms and QOL outcomes compared to ready-made oral

devices, based on available RCTs. Oral appliances may be an appropriate alternative in patients who refuse or cannot tolerate PAP devices. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who use neuromuscular electrical tongue stimulation, the evidence includes 1 RCT and 5 prospective single-arm studies (3 with overlapping patient populations). Relevant outcomes are symptoms, functional outcomes, and QOL. The RCT found high adherence to the eXciteOSA device treatment protocol, and exploratory analyses showed improvements in respiratory event index [REI], apnea index, and hypopnea index relative to a sham control but no significant changes in Epworth Sleepiness Scale (ESS) scores. The study was limited by sample size and short follow-up period. The single-arm studies suggest that eXciteOSA may reduce snoring intensity and improve sleep quality, but improvements on the Apnea-Hypopnea Index (AHI) were mixed. Studies were limited to evaluations after the 6-week course of therapy or 2 weeks post-intervention. Larger, well-designed, controlled studies are needed to evaluate improvement in patients who meet the criteria for treatable OSA, to assess continued use after the 6-week trial period, and the durability of observed benefits. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments (e.g., palate expansion, expiratory positive airway pressure [EPAP], oral pressure therapy, supine vibration), the evidence includes RCTs, prospective single-arm studies, and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on nasal EPAP devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, smaller RCTs, and a systematic review that did not include the industry-sponsored RCT. The main finding of the industry-sponsored RCT was a decrease in the apnea/hypopnea index (AHI), with a minor impact on oxygenation, and a decrease in Epworth Sleepiness Score (ESS). One small RCT with 22 patients found no benefit of an oral EPAP therapy device when added to an oral appliance. One nonrandomized comparative trial with historical controls and a retrospective chart review evaluated a daytime sleep procedure (PAP-NAP) to reduce resistance to CPAP titration or use. Additional study is needed to evaluate the efficacy of this intervention. Several RCTs, observational studies, and a meta-analysis have been published with a sleep positioning device that vibrates when the individual is in a supine position. Drop-out rates were high and long-term compliance is unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Rationale

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

POSITIVE AIRWAY PRESSURE DEVICES

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.^{4,5} 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 individuals. PAP initiation in the home had equivalent effects on individual outcomes compared to in-laboratory titration, and there were no clinically significant differences in individual 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 the effect of CPAP on clinical outcomes.⁶

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 individuals 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.⁷⁻¹⁰ As indicated in the AHRQ report, increased compliance with APAP devices has not been well-documented in clinical trials.^{11,12,13} 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.¹⁴ They included 10 trials with a total of 7266 individuals 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.¹⁵ 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 individuals from the Sleep Heart Health Study who had obesity and severe OSA.¹⁶ For the 81 individuals 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 individuals 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).¹⁷ 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 individual 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 H₂O. 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 individuals 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 individuals without a diagnosis of OSA over 21 years of available data.¹⁸ In multivariate analysis, the risk of respiratory complications was increased for both diagnosed and undiagnosed OSA individuals compared with controls (odds ratio, 2.08; $p < .001$). The risk of cardiovascular complications, primarily cardiac arrest and shock, was higher in OSA individuals 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 individuals 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

Systematic Reviews

In the AHRQ report (2011) on the diagnosis and treatment of OSA in adults, the strength of the evidence that mandibular advancement devices (MADs) improve sleep apnea signs and symptoms was rated moderate.⁶ More recently, 2 systematic reviews with meta-analysis have compared CPAP with oral devices for the management of OSA.^{19, 20} Pattipati et al (2022)

identified literature comparing CPAP with MADs in mild to severe OSA.¹⁹ A total of 8 RCTs were included in the meta-analysis with a duration of treatment ranging from 4 to 520 weeks. Results demonstrated that CPAP was superior to MADs for reducing post-treatment AHI and lowest post-treatment oxygen desaturation. However, there was no statistically significant difference in the mean post-treatment ESS scores between CPAP and MADs groups.

Another systematic review of the evidence on the treatment of OSA with oral appliance therapy was performed by Ramar et al (2015), as part of an update of practice guidelines by American Academy of Sleep Medicine and the American Academy of Dental Sleep Medicine.²⁰ 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 a first-line therapy for treating OSA. The baseline demographics in regard to racial and ethnic diversity were not reported in either review. Additional meta-analyses have supported these findings by reporting pooled improvements from baseline following MADs in AHI, ESS, and ODI for durations over 1 year and within mild, moderate, and severe OSA during stratified analysis.^{21,22}

Ready-made Versus Custom-made Mandibular Advancement Devices

Randomized Controlled Trials

Johal et al (2017) reported on a randomized crossover trial of ready-made vs custom-made mandibular repositioning devices.²³ Twenty-five individuals with mild-to-moderate OSA (mean AHI, 13.3 events per hour; range, 10.9-25 events per hour) were randomized to a 3-month trial of a ready-made or the custom-made device, with a 2-week washout between treatments. An overnight home sleep study was performed at baseline and on the last night of the 3-month trial period. Individuals used the custom-made device for more nights per week (7 vs 3, $p=.004$) 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 individuals 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 SHA) was more frequent with the ready-made device (36%) than with the custom device (4%), while an ESS score of at least 10 was more frequent during the ready-made phase (66%) than with the custom-made phase (33%). An improvement in the QOL score was observed only during the custom-made device phase.

Another randomized crossover study by Bosschieter et al (2022) reported on results from a single-center study in patients with OSA.²⁴ Patients were randomized to either custom or non-custom 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 non-custom MADs ($p<.001$). There were no significant differences found between the custom and non-custom 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]).²⁵ 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.

Neuromuscular Electric Tongue Stimulation

Randomized Controlled Trials

Abreu and colleagues (2023) reported results of a randomized, sham-controlled, double-blinded trial that investigated adherence to daytime electrical stimulation of the tongue with the eXciteOSA device in 40 patients with mild OSA (respiratory event index [REI], 5.0 to 14.9).²⁶ Participants were randomized (1:1) to receive either high-intensity (active) or low-intensity (sham) electrical stimulation for 6 weeks, with the primary outcome being adherence to therapy. Over 90% of participants in each arm adhered to the treatment protocol, using the device for the recommended 20 minutes per day over the 42-day study period. Exploratory analyses revealed a 32.7% decrease in the REI in the active stimulation group at 6-week follow-up (12.9 to 9.6 events per hour; $p < .001$), while no significant change was observed in the sham arm (11.5 vs. 12.6 events per hour; $p = .25$). Both the apnea index (2.0 vs. 1.2 events per hour; $p = .002$) and hypopnea index (11 vs. 8.3 events per hour; $p = .002$) improved after active stimulation but not with sham treatment. No significant changes were noted in the Epworth Sleepiness Scale (ESS) score in either group. The study was underpowered to detect differences in the reported exploratory endpoints further limited by the short follow-up period.

Prospective Cohort Studies

Wessolleck et al (2018) published a pilot study of electrical stimulation of the intraoral musculature with the eXciteOSA device to reduce snoring in individuals without OSA or with mild OSA.²⁷ Individuals with a BMI greater than 32 and an apnea-hypopnea index (AHI) > 15 were excluded. Three of 16 participants did not complete the 6-week treatment protocol of twice daily 20-minute sessions due to technical problems. Patients had a mean age of 43.2 years and a median BMI of 26.6 kg/m². The participants' bed partners reported snoring intensity before, during, and 2 weeks after treatment using a visual analog scale (VAS). Based on the bed partners' reports, snoring intensity was significantly reduced from baseline levels, and this reduction was maintained at 2-week follow-up post-treatment (mean, 5.6 [Standard deviation {SD}, 1.1] vs. 3.3 [SD, 2.4]; $p < .05$). There were no reports of unexpected adverse events.

Three studies reported on an overlapping population from the same single-arm clinical trial (NCT03829956).^{28,29,30} Trial participants used the eXciteOSA 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.²⁸ Patients with a body mass index (BMI) greater than 35 and AHI greater than 15 were excluded. Participants had a mean age of 46.45 and a mean BMI of 26.78 kg/m². For the 70 patients who completed the study, snoring time decreased by 48% and bed partners reported an average reduction of 40% in snoring. 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 [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 per 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%).

Baptista et al (2021) reported the results of a study in which eXciteOSA was administered to 125 patients with a complaint of snoring and an AHI less than 15, 50 participants had an AHI of less than 5 and were considered primary snorers.²⁹ Participants had a mean age of 45.71 and a mean BMI of 27.02 kg/m². Only 1 participant withdrew due to inability to tolerate the treatment, 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.

Nokes et al (2023) conducted a prospective study of 70 patients with mild obstructive sleep apnea (AHI range 5 to 15 events per hour) who were treated with eXciteOSA.³⁰ Patients with a BMI greater than 35 were excluded. The median age was 49, and the median BMI was 27.7 kg/m². Five (7%) participants were excluded or withdrew prior to outcome assessment. The AHI decreased from 10.2 at baseline to 6.8 events/hour ($p<.01$) after treatment, and in the subset of 51 responders, the AHI decreased from 10.4 to 5.0 events per hour ($p<.01$). Objective snoring time decreased from 36.5% to 21.5% ($p<.01$), and bed partner-reported snoring decreased from 6.3 to 3.9 on a visual analog scale ($p<.01$). The ESS improved from 8.7 to 5.3 points ($p<.01$), and the PSQI from 7.3 to 5.9 points ($p<.01$). Adherence with the device was 85% (range 57 to 100%), and adverse events were minor and transient.

Nokes et al (2022) published a prospective study of 20 patients with simple snoring or mild OSA (AHI < 15 events/hour) who were treated with transoral neuromuscular stimulation using the eXciteOSA device for 4-6 weeks.³¹ Patients with a BMI greater than 35 were excluded. The mean age was 40, and the mean BMI was 26.3 kg/m². Although there was no significant change in AHI, treatment was associated with a significant improvement from baseline in tongue endurance measured by the Iowa Oral Performance Instrument (21.7 to 37.0 seconds; $p=.03$), sleep quality measured by the PSQI (5.7 to 4.9; $p=.03$), and sleep efficiency measured by polysomnography (75% to 84%; $p=.002$). Median utilization of the device was 67% of days with 2 completed 20-minute sessions.

Section Summary: Neuromuscular Electric Stimulation

One RCT and 5 prospective single-arm studies (3 with overlapping patient populations) have investigated the use of the eXciteOSA device for neuromuscular electrical stimulation in patients with primary snoring or mild obstructive sleep apnea (OSA). The RCT found high adherence to the device's treatment protocol, and exploratory analyses showed improvements in respiratory event index [RHI], apnea index, and hypopnea index relative to a sham control but no significant changes in Epworth Sleepiness Scale (ESS) scores. The study was limited by its small sample size and short follow-up period. The single-arm studies suggest that

eXciteOSA may reduce snoring intensity and improve sleep quality, but the effects on the Apnea-Hypopnea Index (AHI) were mixed. Studies were limited to evaluations after the 6-week course of therapy or 2 weeks post-intervention. Larger, well-designed, controlled studies are needed to evaluate improvement in patients who meet the criteria for treatable OSA, to assess continued use after the 6-week trial period, and the durability of observed benefits.

NOVEL OBSTRUCTIVE SLEEP APNEA TREATMENTS

Palate and Mandible Expansion

Case Series

Singh et al (2016) reported on a series of 15 consecutive individuals with severe sleep apnea who were treated with a DNA Appliance or mRNA Appliance.³² All individuals had failed to comply with CPAP. Pre- and post-treatment AHI was assessed in a home sleep apnea test without the oral appliance. AHI decreased from a mean 45.9 events per hour to 16.5 ($p < 0.01$) after a mean 9.7 months of treatment.

Singh et al (2016) and Cress (2017) reported on a series of 19 individuals who had mild-to-moderate OSA who were treated with a DNA or mRNA Appliance.³³ Only individuals who complied with oral appliance wear were included in the study. The mean AHI was reduced from 12.85 to 6.2 events per hour ($p < .001$) with the appliance, while the Oxygen Saturation Index 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 PSG, uncertain blinding of the physician evaluating the sleep study, the small number of individuals studied, the lack of intention-to-treat analysis, and the lack of long-term follow-up.

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 use of a daytime abbreviated sleep study to acclimate individuals with complex insomnia to PAP.³⁴ Individuals had been referred by psychiatrists or primary care physicians for unspecified insomnia conditions, insomnia due to a mental disorder, or hypnotic dependence. Nearly all individuals had anxiety, fear, and/or resistance regarding PAP therapy or the diagnosis of OSA. Thirty-nine individuals who would not complete a titration protocol (full-night or split-night) were offered a daytime procedure (PAP-NAP) prior to night-time titration. The PAP-NAP protocol had 5 components: pretest instructions to maximize chances for daytime napping; introduction of PAP therapy addressing barriers to use; type 3 monitoring hookup (10 channels without electroencephalography [EEG] leads); PAP therapy during one to two hours in bed in which the individual had the opportunity to fall asleep with the mask in place; and post-test follow-up. Thirty-five of 39 nap-tested individuals subsequently scheduled and completed an overnight titration or split-night study with full PSG. The effect of the PAP-NAP intervention on compliance was compared with historical controls ($n=38$) who had insomnia, mental health conditions, and OSA with resistance to CPAP who completed titration. A prescription for PAP therapy was filled by 85% of the PAPNAP group compared with 35% of controls. Regular use during a 30-day period was recorded by the PAP device in 67% of the intervention group and in 23% of controls. Adherence, defined as at least 5 days a week with an average of at least 4 hours a day, was 56% in the PAP-NAP group and 17% in controls.

Retrospective Cohort Study

The same group of investigators (Ulibarri et al, 2020) conducted a retrospective chart review of 139 individuals who were diagnosed with OSA or upper airway resistance syndrome between 2011 and 2016 and had initially refused titration of PAP but accepted a trial of PAP with a PAP-NAP.³⁵ The most common risk factors for initial PAP rejection were depression, insomnia, claustrophobia, and trauma exposure, while the most common indications for PAP-NAP were general reluctance, anxiety, and claustrophobia. The procedure averaged about 3 hours, which included 83 + 30 min of coaching and 107 + 57 min napping; 99% of individuals experienced expiratory pressure intolerance and a majority preferred an alternative PAP mode for the nap period. Use at follow-up was determined by renewal request for PAP supplies, re-titration, clinic appointment or other contact with staff. The duration of use is unclear from the report, but at the time of follow-up 71% of individuals who had initially refused PAP were considered users and 29% were non-users.

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.³⁶ Study designs included 10 conference papers and 8 publications (case series, cohort studies, RCTs). For individuals included in the meta-analysis (n=345), AHI decreased from 27.32 to 12.78 events per hour ($p<.001$). For 359 individuals, ESS score modestly improved from 9.9 to 7.4 ($p<.001$). Data from the Berry et al (2011) RCT (described 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.³⁷ Two hundred fifty individuals with OSA and an AHI of 10 or more events per hour were randomized to nasal EPAP (n=127) or to a sham device (n=123) for 3 months. PSG was performed on 2 nights (device-on, device off, in a random order) at week 1 (92% follow-up) and after 3 months of treatment (78% follow-up). EPAP reduced median AHI from 13.8 to 5.0 events per hour (-52.7%) at week 1 and from 14.4 to 5.6 events per hour (-42.7%) at 3 months. This reduction in AHI in the treatment group was significantly greater (-7.3% at week 1, -10.1% at 3 months) than in the sham group. Over 3 months, the decrease in ESS score was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1-point difference in ESS score is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol individuals who had an AHI of 5 or more events per hour on the device-off PSG night. The oxygenation results (Oxygenation Desaturation Index and percent of total sleep time with oxygen saturation <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduction to less than 10 events per hour (if device-off AHI was ≥ 10 events per hour), was greater in the EPAP group at 1 week (62% vs 27.2%) and at 3 months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of individuals in the EPAP group and by 34% of individuals in the sham group, with 7% of individuals in the EPAP group discontinuing due to adverse events. Overall, the validity of these results was limited by the high dropout rate, and the clinical significance of the results is uncertain.

Kryger et al (2011), in an open-label extension of the 2011 randomized study by Berry et al (2011), evaluated 12-month safety and durability of the treatment response in individuals who had an initially favorable response to EPAP.³⁸ Included were 41 (32%) of the 127 individuals in the EPAP arm of the study who used the device for an average of at least 4 hours per night on at least 5 nights a week during months 1 and 2 and had at least a 50% reduction in AHI, or reduction to less than 10 events per hour, compared to the device-off PSG. Of the 51 (40%) of 127 eligible individuals, 41 enrolled in the extension study, and 34 (27%) of 127 were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events per hour; the percentage of individuals who met criteria for success was not reported. The arousal index was modestly decreased (from 23.9 to 19.0). After 12 months of treatment, the ESS score decreased from 11.1 to 6.0. The median percentage of reported nights used (entire night) was 89.3%. Device-related adverse events were reported by 42% of individuals, most frequently having difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study was limited by its inclusion only of responders and by the potential for a placebo effect on the ESS score. However, the data suggested that some individuals might have responded to this device, and the individual compliance data might indicate a positive effect on daytime sleepiness that leads to continued use of the device in about 25% of individuals. Additional controlled studies are needed to distinguish between these alternatives.

Kureshi et al (2014) reported on a small (n=14) double-blind, pilot, crossover RCT of EPAP in children to evaluate efficacy and compliance with this new treatment.³⁹ PSG with EPAP or a placebo device showed a significant mean improvement in Obstructive Apnea Index with EPAP (0.6 versus 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.

Sleeper et al. (2022) conducted a laboratory comparison to test the expiratory pressures generated by the following four expiratory positive airway pressure (EPAP) devices: ULTepap, Provent, Bongo Rx, and Theravent.⁴⁰ Measurement of the expiratory and inspiratory pressures were captured by a Respirationics digital pressure manometer. Prior to the measurement of each of the devices, the manometer was calibrated to zero. The authors found the expiratory pressures generated by ULTepap and Provent were similar, with ULTepap being slightly lower at all flow rates. The Bongo Rx and Theravent devices produced substantially lower back pressures than Provent and ULTepap, in addition to Bongo Rx having a significantly lower flow rate. In summary, the authors felt not all FDA cleared EPAP devices provide similar mechanical results and additional clinical trials comparing short- and long-term efficacy, patient satisfaction, and adherence are warranted. Limitations included lack of OSA specific outcomes and lack of clinical evidence of efficacy.

Oral and OroNasal Pressure Therapy

Randomized Controlled Trials

Lai et al (2019) reported a study with 22 individuals with OSA who incomplete responders to an oral appliance (AHI > 5) were.⁴¹ They were assessed with the oral appliance plus either an oral or an oronasal EPAP. Both the oral and oral/nasal devices were studied in the same night (split night PSG); the order of the EPAP devices was randomized. Power analysis indicated that 20 participants would be sufficient to detect an AHI difference of 7 between conditions. Five individuals (23%) had at least a 50% reduction in total AHI with the oral EPAP compared

to the oral appliance alone, while 10 individuals (45%) had a 50% reduction in AHI with the combined oral and nasal EPAP valves. Neither of these was statistically significant. Only 2 individuals (9%) achieved an AHI of less than 5 with the oral EPAP device compared to 9 (41%) with the combined oral and nasal valves. However, sleep efficiency was disrupted with the oronasal EPAP valves.

NightBalance Sleep Position Trainer

Systematic Review

For some individuals, apneic events occur predominantly when the individual is supine. Sleep position trainers for individuals with positional OSA are intended to reduce time on the back and can range from supine vibration alarm devices to tennis balls sewn into the back of night wear. A Cochrane review by Srijithesh et al (2019) evaluated positional therapy for obstructive sleep apnea.⁴² The meta-analysis included 3 crossover studies with a vibration alarm and 5 with specially designed pillows or semi-rigid backpacks. The review found low to moderate evidence that CPAP was more effective than positional therapy in improving AHI (n=72), but positional therapy was more effective than no treatment for improving outcomes (n=251) and may have better adherence than CPAP. All of the studies were short-term and the long-term effect was uncertain.

Randomized Controlled Trials

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

Eijsvogel et al (2015) compared the first generation sleep position trainer to "the tennis ball technique" with commercially available air pillows on the back in 55 participants.⁴³ Both devices reduced supine position by a median of 100% and reduced the median supine AHI to 0 events/h at the 1 month sleep study. There were no significant differences between the groups for the ESS, VAS, and sleep-related quality of life data. Objective compliance data for the entire month showed that the median hours used per night was numerically higher but did not achieve statistical significance due to variability (6.5 vs 4.5, $p=.078$). There were significant increases in the percentage of individuals who used the device every day (51.7% vs 15.4%, $p=.005$) and in effective compliance, measured by use for at least 4 hours per night on at least 5 days per week (75.9% vs 42.3%, $p=.011$). Compliance in both groups decreased over the month of the study. Continued use after the month trial was not evaluated, and the clinical significance of an increase in compliance without a difference in sleepiness or quality of life is uncertain.

de Ruiter et al (2018) evaluated 12 month efficacy of the NightBalance Sleep Position Trainer compared to oral appliance therapy in a multicenter randomized trial of participants with positional OSA.⁴⁴ This was a follow-up to a previously published 3-month study. There were no significant differences between the 2 groups in AHI, ESS, FOSQ, or the average hours of use per night. However, 41% of the participants had dropped out of the study by the 12 month follow-up due to adverse events or lack of efficacy, and results in the publication represent only those individuals who had remained in the study. Sensitivity analysis with intention-to-treat was reported in a supplement, and in the worst case scenario, AHI decreased by 1 with NightBalance and by 5.5 with the oral appliance. With intention-to-treat and last observation carried forward, the average hours of use per night decreased to 3.1 for NightBalance and 2.7 for the oral appliance ($p=.522$).

Berry et al (2019) compared the NightBalance Sleep Position Trainer to APAP in a 6-week randomized crossover trial in treatment naive individuals (N=117) with exclusive positional OSA.⁴⁵ The investigators selected a non-inferiority margin of 5 events/h for the AHI endpoint and 30 minutes for adherence. The sleep position trainer achieved non-inferiority with a difference of 3.58 events/h. APAP was more effective than the Sleep Position Trainer in terms of the AHI ($p < .001$), but adherence was better with NightBalance ($p < .001$). There were no significant differences between the treatments for total sleep time, sleep efficiency, sleep latency, wake after sleep onset, or the duration of sleep stages. The ESS was statistically better in the APAP phase, although this did not achieve clinical significance. Post-hoc analysis of participants who had a baseline ESS score of greater than 10 showed that while both treatments improved the ESS, APAP was more effective (final ESS: 9.5 vs 11.5, $p < .001$). Individuals reported that the NightBalance device was easier to use and more comfortable and would choose this device, but thought that APAP was more effective in treating the sleep apnea.

Table 4. Summary of Key RCT Characteristics

Study	Countries	Sites	Design	Participants	Interventions ¹	
Eijssvogel et al (2015)	EU		Randomized parallel arm	55 individuals with mild to moderate symptomatic POSA who had been referred to a tertiary care center	Active 4 weeks with the first generation NightBalance Sleep Position Trainer (n=29)	Comparator 4 weeks with commercially available inflated airbags on the back (n=26)
de Ruiter et al (2018)	EU	2	Randomized parallel arm	99 individuals with mild to moderate POSA, defined as $AHI \geq 2$ times nonsupine AHI and total $AHI < 15$ events/h	12 mo follow-up with NightBalance Sleep Position Trainer (n=48, 29 completed)	12 mo follow-up with OAT with an imbedded microchip to monitor usage (n=51, 29 completed)
Berry et al (2019) (POSAtive)	US	11	Randomized crossover	117 treatment naive individuals with exclusive POSA, defined as a supine $AHI \geq 2$ times nonsupine AHI and a nonsupine $AHI < 10$ events/h; total AHI was at least 15 events/h (moderate to severe OSA).	6 weeks with the NightBalance Sleep Position Trainer	6 weeks with APAP

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

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

Table 6. Study Relevance Limitations

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

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

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

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

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 7. Study Design and Conduct Limitations

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

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

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

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

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

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

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per individual; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Observational Studies

Van Maanen and de Vries (2014) conducted a prospective study in individuals with mild to moderate positional OSA.⁴⁶ There were 145 individuals who were asked to use the Sleep Position Trainer for 6 months with the option to keep the device at the end of the study. However, the data could not be retrieved in 39 individuals, leaving 106 with objective data. The time spent supine decreased from 21% at baseline to 3% in the 53 participants (36%) who provided objective measurements at 6 months. Subjective measures (median ESS 11 to 8; PSQI 8 to 6; and FOSQ 87 to 103) were significantly improved compared to baseline, but only 66 participants out of the 145 (45%) completed the questionnaires. Analysis was per protocol rather than intent-to-treat, raising questions about the validity of the results. Regular use, defined as at least 4 hours a night over at least 5 nights, was 71.2% averaged over the trial period. Objective use of the device for at least 1 hour per night decreased from 106 individuals at the start of the study to less than 60 by 6 months. It is uncertain whether the number of individuals using the device would be as high as this outside of a trial.

Beyers et al (2018) invited individuals to participate in a 1 month trial of the sleep position trainer as part of a standard clinical pathway at a university hospital.⁴⁷ In order to qualify for the trial, individuals were required to have an overall AHI of > 5 events/h, a supine AHI at least twice as high as the non-supine AHI, and 10% to 90% of total sleep time spent in the supine position. Out of 101 individuals, 79 (78%) completed the 28 day trial period. There were 45 responders who had an overall reduction in Respiratory Event Index (REI) from 11.3 to 3.4 and a reduction in supine REI from 28.9 to 2.3. For the 44 individuals (43% of 101) who decided to purchase the device, 27 (27% of total) were considered responders. Reasons for not purchasing the device included persistent daytime sleepiness, intolerance to the vibrations, and preference for other treatment options. Due to the relatively low percentage of individuals who responded and chose to purchase the device, the investigators recommended a trial period. Treatment success over longer than the 1 month trial period was not evaluated. Similar findings were reported in a separate clinical study of 51 consecutive individuals with positional OSA who had a 1 month trial of the NightBalance device.⁴⁷ About half of individuals (n=27) were considered adherent during the trial, and half of those (n=13) wanted to purchase the device. Ten individuals had a higher response to the vibrations and were considered cured.

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.

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

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.

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.⁴⁹ 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.^{50,51} 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.⁵² The levels of recommendation are "standard"(generally accepted individual-care strategy, with a high degree of certainty; level 1 to 2 evidence), "guideline"(moderate degree of clinical certainty; level 2 to 3 evidence), or "option" (uncertain clinical use; insufficient or inconclusive evidence).

Treatment with 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).
- Auto titrating positive airway pressure (APAP) can be considered in CPAP-intolerant patients (Consensus).

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

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

The AASM (2019) also published a clinical practice guideline on the treatment of OSA with PAP that was based on a systematic review of the evidence.^{4,5} "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 oral appliance therapy.²⁰ The two societies provided a recommendation of "standard" that sleep physicians consider prescription of oral appliances, rather than no treatment, for adults with OSA who are intolerant of CPAP therapy or prefer alternative therapy. The quality of evidence was rated as moderate. "Guideline" recommendations were provided for the use of custom, titratable appliance over non-custom oral devices, that qualified dentists provide oversight, which 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.

In 2025, the AASM issued a statement following FDA approval of Zepbound for adults with moderate-to-severe OSA and obesity.⁶² The AASM recommends that treatment with Zepbound be evaluated by an accredited sleep center and highlights its role as an adjunctive option, particularly for patients whose OSA is primarily obesity-driven. The statement says that Zepbound is not universally effective and should be considered alongside established therapies—such as PAP, oral appliances, or upper airway stimulation—especially when anatomical factors contribute to OSA, and clinicians should counsel patients on the importance of sustained weight loss and potential adverse effects.

American Heart Association

In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease.⁵³ 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] ≥ 15 events per hour or AHI (or REI) ≥ 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).⁵⁴ 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:

- "OSA is highly prevalent in the bariatric patient population...."
- [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.
- 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.
- 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 statement on the long-term effects and treatment of mild OSA in adults.⁵⁵ The Society's systematic review concluded:

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

National Institute for Health and Care Excellence

NICE provides guidance on medical management in individuals with varying degrees of OSA.⁵⁶ 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.

NICE published guidance on daytime intraoral neuromuscular electrical tongue stimulation for obstructive sleep apnea in 2023.⁵⁷ A rapid review of evidence identified 1 single-arm trial and 1 pilot study and also considered 2 submissions from patient organizations about the procedure. NICE recommended that the procedure should only be used in a research setting due to an inadequate quantity and quality of evidence and that further adequately powered RCTs and analysis of observational data should be used to assess efficacy, safety, and adherence.

VA/DOD Clinical Practice Guidelines

The Department of Veterans Affairs (VA) and the Department of Defense (DOD) published a research statement on the management of chronic insomnia disorder and OSA (2025).⁶³

For treatment of OSA, we recommend one or more of the following evidence-based therapies, depending on patient values and characteristics (Strong level of evidence for, Newly added):

- Mandibular advancement devices
- PAP
- Referral for surgical evaluation

For treatment of mild to moderate OSA (Event Index <30 per hour), we suggest either mandibular advancement devices or PAP as first-line therapy options (Weak level of evidence for, Amended).

For the treatment of positional OSA, we suggest positional therapy (Weak, Newly added).

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2017) reviewed the evidence on screening for OSA in adults and concluded that “the current evidence is insufficient to assess the balance and harms of screening for obstructive sleep apnea (OSA) in asymptomatic adults. Evidence on screening tools to accurately detect persons in asymptomatic populations who should receive further testing and treatment of subsequently diagnosed OSA to improve health outcomes is lacking, and the balance of benefits and harms cannot be determined.”^{58,59}

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in May 2025 identified over 200 ongoing studies on the medical management of OSA.

Regulatory Status:

A variety of oral appliances have been cleared for marketing clearance by U.S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of snoring and mild-to-moderate OSA, including the Narval CC™, Lamberg SleepWell Smarttrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, DeSRA,

Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snorar™ 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.

In December 2024, the FDA approved Zepbound® (tirzepatide), a once-weekly GLP-1/GIP receptor agonist, as a treatment option for moderate-to-severe OSA in combination with exercise and a reduced-calorie diet.

Novel devices for OSA diagnosis and treatment are described in Table 8.

Table 8. Novel Devices for OSA Diagnosis and Treatment

Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
Diagnosis					
Accusom	Novasom, Inc	The ACCUSOM device is a battery and line-powered ventilatory effort recorder. The ACCUSOM device is indicated for use in the diagnostic evaluation of adults with possible sleep apnea.	K110486	MNR	2011
SOMNOtouch RESP	Somnomedics, GMBH	The SOMNOtouch RESP is a portable physiological signal recorder. It is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of sleep disorders and sleep related respiratory disorders of adult patients.	K140861	MNR	2015
SleepImage System	MyCardio	Software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor to aid in the evaluation of sleep disorders.	K163696	MNR	2017
ZMachine synergy	Consolidated Research of Richmond, Inc	The Zmachine Synergy is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep disorders.	K172986	OLV, OMC, MNR	2017
ApneaTrak	Cadwell Industries, Inc	The Cadwell ApneaTrak device is intended for home sleep testing, including the acquisition of physiological and environmental data. The recorded signals are then transmitted to a PC so that they can be viewed. ApneaTrak is intended for use on patients older than 2 years of age.	K192624	MNR	2020

Belun ring	Belun Technology Company Limited	The Belun Sleep System BLS-100 is a wearable device intended to record, analyze, display, export, and store biophysical parameters to aid in evaluating moderate to severe sleep-related breathing disorders of adult patients suspected of sleep apnea.	K211407	MNR	2021
ANNE Sleep	Sibel, Inc.	ANNE Sleep is a wearable sensor system intended for use in the collection, analysis, display, and storage of physiological parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea.	K220095	MNR	2022
BresoDX1	Bresotec Inc	BresoDX1 is indicated for use as an aid in the diagnosis of moderate to severe sleep apnea in adult patients. BresoDX1 records a patient's physiological signals during sleep and scores apneas and hypopneas.	K220012	MNR	2022
Cerebra Sleep System	Cerebra Medical, Ltd	The Cerebra Sleep System is an integrated diagnostic platform that acquires, transmits, analyzes, and displays physiological signals from adult patients, and then provides for scoring (automatic and manual), editing, and generating reports. The system uses polysomnography (PSG) to record the electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), electromyogram (EMG), accelerometry, acoustic signals, nasal airflow, thoracic and abdomen respiratory effort, pulse rate, and oxyhemoglobin saturation, depending on the sleep study configuration.	K213007	OLV	2022
NightOwl	Ectosense Nv	The NightOwl is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea.	K220028	MNR	2022
Sunrise	Sunrise SA	The Sunrise device is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years	K222262	MNR	2022

		and older with suspicions of sleep breathing disorders.			
WatchPAT	Itamar Medical, Ltd	The WatchPAT ONE (WP1) device is a noninvasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position.	K223675	MNR	2022
AcuPebble OX100	Acurable Limited	AcuPebble Ox100 is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of adult patients with, or with suspected, obstructive sleep apnea (OSA)	K222950	MNR	2023
Onera STS	Onera B.V	Onera STS measures and records multiple physiological parameters from a patient during a sleep study which are used by clinicians to make a decision on the diagnosis of sleep disorders.	K223573	MNR	2023
Wesper Lab	Wesper, Inc	The Wesper Lab is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. Wesper Lab records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep apnea by trained personnel.	K221816	MNR	2023
WithingsSleep Rx	Withings	The device is indicated to record a patient's Withings index during sleep as an aid for diagnosis of OSA. The Withings Sleep Rx is also indicated to record heart rate and movement in an automatic, contactless manner. The device is designed for use in the home screening of adults with suspected sleep breathing disorders. Results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation.	K231667	MNR	2024
AcuPebbleOx200	Acurable Limited	AcuPebble Ox200 is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of	K243092	MNR	2025

		biophysical parameters to aid in the evaluation of adult patients with, or with suspected, OSA. The device is primarily intended for home setting use (although can also be used in healthcare settings) under the direction of a healthcare professional.			
TipTraQ (TTQ001)	PranaQ Pte.Ltd	The TipTraQ is a wearable device intended for aiding sleep apnea evaluation/diagnosis for adult patients suspected of sleep apnea in both home-based and clinical-use environments.	K243268	MNR	2025
SANSA HSAT	HuxleyMedical	The Huxley Home Sleep Apnea Test (SANSA) is a wearable device intended for use in the recording, analysis, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adults suspected of sleep apnea. The device is intended for the clinical and home use under the direction of a healthcare professional.	K244027	MNR	2025
Treatment					
Provent®	Ventus Medical	Nasal expiratory resistance valve.	K102404	OHP	2010
ULTEPAP™	BRYGGS Medical, LLC	Nasal expiratory resistance valve.	K191728	OHP	2020
Winx™	Apnicure, Inc	Oral pressure therapy.	K122130	OZR	2012
mRNA Appliance®	BioModeling Solutions	Expandable oral appliance for the treatment of snoring and mild-to-moderate OSA	K130067	LRK	2014
NightBalance Lunoa System	Philips	The positional sleep trainer is worn with an elasticized chest strap and is intended to keep individuals with positional obstructive sleep apnea from sleeping in the supine position.	K180608	MYB	2018
eXciteOSA®	Signifier Medical Technologies	The device delivers neuromuscular stimulation during the day to strengthen the tongue in order to reduce snoring and mild sleep apnea. It is used for 20 minutes once a day for a period of 6 weeks, and once a week thereafter.	K223446	QNO	2021
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
CARE (Complete Airway	Vivos Therapeutics, Inc	The device is intended to reduce nighttime snoring and to treat mild and moderate obstructive sleep	K230947	LRK; LQZ	2023

Repositioning and/or Expansion)		apnea in adults, 18 years of age and older. The device is also intended to treat moderate and severe obstructive sleep apnea in adults, 18 years of age and older along with positive airway pressure devices and/or myofunctional therapy, as needed.			
airVata™	Gelb Practice Solutions, Inc.	The device is intended to reduce nighttime snoring and to treat mild, moderate, and severe OSA in adults age 18 years and older. The device is worn while sleeping to support the lower jaw in a forward position prescribed by the dentist. The appliance is removable by the patient.	K240427	LRK; LQZ	2024
EMA 3D	EMA Sleep Inc.	The EMA 3D is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate OSA in adults.	K232735	LRK; LQZ	2024
DNA Appliance	Vivos Therapeutics	The device is intended to reduce nighttime snoring and to treat moderate and severe OSA in children 6-17 years of age who are diagnosed with snoring and/or moderate or severe OSA and need orthodontic treatment.	K234089	LRK; LQZ	2024
Rest Assure System	Somnomed, Inc	The device is intended to be used in the treatment of snoring and mild to moderate OSA in patients over 18. Rest Assure has the capability to record and monitor patient compliance to oral device/appliance therapy.	K233497	LRK; LQZ	2024

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

Government Regulations

National:

NCD – 240.4 – Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea, 8/4/08.

Nationally Covered Indications

Effective for claims with dates of service on and after March 13, 2008, the Centers for Medicare & Medicaid Services (CMS) determined that CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under 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 a clinical evaluation and a positive:
 - a. attended PSG performed in a sleep laboratory; or
 - b. unattended HST with a Type II home sleep monitoring device; or
 - c. unattended HST with a Type III home sleep monitoring device; or
 - d. 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 criterion using the AHI or RDI are met:
 - a. AHI or RDI greater than or equal to 15 events per hour, or
 - b. 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 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 a 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 one or more of the following questions:
 - a. 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 Type II, III & IV HST in identifying subjects with OSA who will respond to CPAP?
 - b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III & IV HST, does CPAP cause clinically meaningful harm?

The study must meet the following additional standards:

- c. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- d. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- e. The research study does not unjustifiably duplicate existing studies.
- f. The research study design is appropriate to answer the research question being asked in the study.

- g. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- h. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is Food and Drug Administration-regulated, it also must be in compliance with 21 CFR Parts 50 and 56.
- i. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
- j. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
- k. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the individual has no other viable treatment options.
- l. The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.
- m. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured, including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned for publication in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
- n. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- o. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Nationally Non-covered Indications

Effective for claims with dates of services on and after March 13, 2008, other diagnostic tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient.

Local:

CGS Administrators, LLC

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

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

Revision Effective Date: For services performed on or after 8/8/21

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

- A. The beneficiary has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the beneficiary for obstructive sleep apnea testing.
- B. The beneficiary has a Medicare-covered sleep test that meets one of the following criteria (1 - 3):
1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
 2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
 - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
 - b. Hypertension, ischemic heart disease, or history of stroke; or,
 3. If the AHI > 30 or the RDI > 30 and meets either of the following (a or b):
 - a. The beneficiary is not able to tolerate a positive airway pressure (PAP) device; or,
 - b. The treating physician determines that the use of a PAP device is contraindicated.
- C. The device is ordered by the treating physician following a review of the report of the sleep test. (The physician who provides the order for the ORAL APPLIANCE could be different from the one who performed the clinical evaluation in criterion A.)
- D. The device is provided and billed for by a licensed dentist (DDS or DMD).
- If all of these criteria (A-D) are not met, the custom fabricated oral appliance (E0486) will be denied as not reasonable and necessary.

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

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

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

CGS Administrators, LLC

Local Coverage Article: Oral Appliances for Obstructive Sleep Apnea - Policy Article (A52512) Original Effective Date 10/01/2015; Revision Effective Date 8/8/21

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

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

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

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

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

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

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

CGS Administrators, LLC, DME MAC, 17013 - DME MAC, J-B

Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)

Original Effective Date 10/1/2015, Revision Effective Date 1/1/24

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, which must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

DEFINITIONS:

Apnea is defined as the cessation of airflow for at least 10 seconds.

Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the AHI. Sleep time can only be measured in a Type I (facility based polysomnogram) or Type II sleep study (see descriptions below).

The respiratory disturbance index (RDI) is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the RDI. The RDI is reported in Type III, Type IV, and Other home sleep studies.

If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach ≥ 30 events without symptoms or ≥ 10 events with symptoms).

INITIAL COVERAGE:

In this policy, the term PAP (positive airway pressure) device will refer to both a single-level continuous positive airway pressure device (E0601) and a bi-level respiratory assist device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

- I. An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met:
 - A. The beneficiary has a face-to-face clinical evaluation by the treating practitioner prior to the sleep test to assess the beneficiary for obstructive sleep apnea.
 - B. The beneficiary has a sleep test (as defined below) that meets either of the following criteria (1 or 2):
 1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
 2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
 - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
 - b. Hypertension, ischemic heart disease, or history of stroke.
 - C. The beneficiary and/or their caregiver has received instruction from the supplier of the device in the proper use and care of the equipment.

If a claim for an E0601 is submitted and all of the criteria above have not been met, it will be denied as not reasonable and necessary.

- II. An E0470 device is covered for those beneficiaries with OSA who meet criteria A-C above, in addition to criterion D:
 - D. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

Ineffective is defined as documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).

If E0470 is billed for a beneficiary with OSA and criteria A-D are not met, it will be denied as not reasonable and necessary.

A bi-level positive airway pressure device with back-up rate (E0471) is not reasonable and necessary if the primary diagnosis is OSA. If an E0471 is billed with a diagnosis of OSA, it will be denied as not reasonable and necessary.

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not require a new initial face-to-face clinical evaluation or a new sleep test.

If an E0601 device has been used for more than 3 months and the beneficiary is switched to an E0470, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new 3 month trial would begin for use of the E0470.

Coverage, coding and documentation requirements for the use of E0470 and E0471 for diagnoses other than OSA are addressed in the Respiratory Assist Devices (RAD) Local Coverage Determination (LCD) and related Policy Article (PA).

Sleep Tests

Coverage and Payment rules for diagnostic sleep tests may be found in the CMS National Coverage Determination (NCD)240.4.1 (CMS Pub.100-03, Chapter 1, Part 4), the applicable A/B MAC LCDs and Billing and Coding articles. The sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or an inpatient hospital-based or home-based sleep test (HST) (Types II, III, IV, Other).

Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon all of the following:

1. A sleep test (Type I, II, III, IV, Other) that meets the Medicare requirements for a valid sleep test as outlined in NCD240.4.1 and the applicable A/B MAC LCD and Billing and Coding article; and,
2. A sleep test that is approved by the Food and Drug Administration (FDA) as a diagnostic device; and,
3. The sleep test results meet the coverage criteria in effect for the date of service of the claim for the PAP device; and,
4. The sleep test is ordered by the beneficiary's treating practitioner; and,
5. The sleep test is conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating

therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.

For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by:

1. In-person clinical re-evaluation by the treating practitioner with documentation that symptoms of obstructive sleep apnea are improved; and,
2. Objective evidence of adherence to use of the PAP device, reviewed by the treating practitioner.

Adherence to therapy is defined as use of PAP ≥ 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage. If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not reasonable and necessary.

If the treating practitioner re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the beneficiary is benefiting from PAP therapy as defined in criteria 1 and 2 above, continued coverage of the PAP device will commence with the date of that re-evaluation.

Beneficiaries who fail the initial 12 week trial are eligible to re-qualify for a PAP device but must have both:

1. In-person clinical re-evaluation by the treating practitioner to determine the etiology of the failure to respond to PAP therapy; and,
2. Repeat sleep test in a facility-based setting (Type 1 study). This may be a repeat diagnostic, titration or split-night study.

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not change the length of the trial unless there is less than 30 days remaining in the trial period. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31st and 91st day following the initiation of an E0601 and objective documentation of adherence on the E0470 would need to occur prior to the 91st day following initiation of the E0601. If less than 30 days remain in the trial period, the clinical re-evaluation and objective documentation of adherence must occur before the 120th day following the initiation of the E0601.

If an E0601 device was used for more than 3 months and the beneficiary was then switched to an E0470, the clinical re-evaluation must occur between the 31st and 91st day following the initiation of the E0470. There would also need to be documentation of adherence to therapy during the 3 month trial with the E0470.

If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies. For a PAP device dispensed prior to November 1, 2008, if the initial Medicare coverage criteria in effect at the time were met and the criteria for coverage after the first 3 months that were in effect at the time were met, the device will continue to be covered for dates of service on or after November 1, 2008 as long as the beneficiary continues to use the device.

CONCURRENT USE OF OXYGEN WITH PAP THERAPY:

Some beneficiaries may require the simultaneous use of home oxygen therapy and oxygen equipment with a PAP device. To be considered for simultaneous coverage, all requirements in the "Coverage Indications, Limitations and/or Medical Necessity" sections of both the Oxygen and Oxygen Equipment and Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCDs must be met. Consequently, in addition to this LCD, suppliers should refer to the Oxygen and Oxygen Equipment LCD and related Policy Article for additional coverage, coding and documentation requirements.

For beneficiaries with OSA to be considered for oxygen therapy and oxygen equipment, the OSA must be sufficiently treated such that the underlying condition resulting in hypoxemia is unmasked. This must be demonstrated before oxygen saturation results obtained during polysomnography are considered qualifying for oxygen therapy and oxygen equipment. For beneficiaries with OSA, a qualifying oxygen saturation test for the purposes of Medicare home oxygen and oxygen equipment reimbursement may only occur during a titration polysomnographic study (either split-night or stand-alone). The titration PSG is one in which all of the following criteria are met:

1. The titration is conducted over a minimum of two (2) hours; and,
2. During titration:
 - A. The AHI/RDI is reduced to less than or equal to an average of ten (10) events per hour; or,
 - B. If the initial AHI/RDI was less than an average of ten (10) events per hour, the titration demonstrates further reduction in the AHI/RDI; and,
3. Nocturnal oximetry conducted for the purpose of oxygen and oxygen equipment reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings; and,
4. The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation of $\leq 88\%$.

To be eligible for Medicare coverage and payment for home oxygen therapy and oxygen equipment for concurrent use with PAP therapy, the beneficiary must meet all other coverage requirements for oxygen therapy and oxygen equipment. Beneficiaries that qualify for oxygen therapy based on testing conducted only during the course of a sleep test are eligible only for reimbursement of stationary equipment.

Overnight oximetry performed as part of home sleep testing or as part of any other home testing is not considered as eligible to be used for qualification for reimbursement of home oxygen and oxygen equipment (see the "Overnight Oximetry Studies" section of the Oxygen and Oxygen Equipment LCD for additional information).

REPLACEMENT:

This section applies to PAP devices initially provided and covered while the beneficiary was in Medicare fee-for-service (FFS).

If a PAP device is replaced during the 5 year reasonable useful lifetime (RUL) because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period.

If a PAP device is replaced following the 5 year RUL, there must be a face-to-face evaluation by their treating practitioner that documents that the beneficiary continues to use and benefit from the PAP device. There is no requirement for a new sleep test or trial period.

BENEFICIARIES ENTERING MEDICARE:

For beneficiaries who received a PAP device prior to enrollment in fee for service (FFS) Medicare and are seeking Medicare coverage of either rental of the device, a replacement PAP device and/or accessories, both of the following coverage requirements must be met:

1. Sleep test – There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, which meets the Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement PAP device and/or accessories; and,
2. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have a face-to-face evaluation by their treating practitioner who documents in the beneficiary's medical record that:
 - A. The beneficiary has a diagnosis of obstructive sleep apnea; and,
 - B. The beneficiary continues to use the PAP device.

If either criteria 1 or 2 above are not met, the claim will be denied as not reasonable and necessary.

In these situations, there is no requirement for a clinical re-evaluation or for objective documentation of adherence to use of the device.

ACCESSORIES:

Accessories used with a PAP device are covered when the coverage criteria for the device are met. If the coverage criteria are not met, the accessories will be denied as not reasonable and necessary.

The following table represents the usual maximum amount of accessories expected to be reasonable and necessary:

A4604	1 per 3 months
A7027	1 per 3 months
A7028	2 per 1 month
A7029	2 per 1 month
A7030	1 per 3 months
A7031	1 per 1 month
A7032	2 per 1 month
A7033	2 per 1 month
A7034	1 per 3 months
A7035	1 per 6 months
A7036	1 per 6 months

A7037	1 per 3 months
A7038	2 per 1 month
A7039	1 per 6 months
A7046	1 per 6 months

Quantities of supplies greater than those described in the policy as the usual maximum amounts will be denied as not reasonable and necessary.

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products (A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046) that are supplied as refills to the original order, suppliers must contact the beneficiary, and document an affirmative response, prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are expected to end, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the

expected end of the current supply. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee and document an affirmative response, prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request and an affirmative response from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioners that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a three (3) - month quantity at a time.

Either a non-heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating practitioner for use with a covered PAP (E0470 or E0601) device.

Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea - Policy Article (A52467), Original Article Effective Date 10/1/15, Revision Effective Date 8/8/21

Article Text:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Positive airway pressure devices are covered under the Durable Medical Equipment benefit [Social Security Act §1861(s)(6)]. In order for a beneficiary's DME to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Accessories are separately reimbursable at the time of initial issue and when replaced.

No aspect of a home sleep test, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests or to tests conducted in facility-based sleep laboratories.

A liner used in conjunction with a PAP mask is considered comfort/convenience item. There is no additional payment for liners used with a PAP mask. These products should be coded A9270 (Noncovered item or service) in accordance with the Medicare Benefit Policy Manual

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO 42 CFR 410.38(g)

42 CFR 410.38(g) requires a face-to-face evaluation and a specific written order prior to delivery for specified HCPCS codes. CMS provides a list of the specified codes, which is periodically updated, located [here](#).

Claims for the specified items subject to 42 CFR 410.38(g) that do not meet the requirements specified in the LCD-related Standard Documentation Requirements Article will be denied as statutorily noncovered – failed to meet statutory requirements.

If the supplier delivers the item prior to receipt of a written order, it will be denied as statutorily noncovered. If the written order is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

INITIAL EVALUATION

For the initial evaluation, the report would commonly document pertinent information about the following elements but may include other details. Each element would not have to be addressed in every evaluation.

History

- Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches;
- Duration of symptoms
- Validated sleep hygiene inventory such as the Epworth Sleepiness Scale (see Appendices of related LCD)

Physical Exam

- Focused cardiopulmonary and upper airway system evaluation
- Neck circumference
- Body mass index (BMI)

A dispensing order is not sufficient to provide these items. A Written Order Prior to Delivery (WOPD) is required.

The DMEPOS supplier must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.

Suppliers are reminded that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient information included in the medical record to demonstrate that all of the applicable coverage criteria are met. This information must be available upon request.

For beneficiaries changing from an E0601 to E0470 due to ineffective therapy while on E0601 (either during a facility-based titration or in the home setting), the treating practitioner must document that both of the following issues were addressed prior to changing to an E0470 device:

- A. Interface fit and comfort. An appropriate interface has been properly fit and the beneficiary is using it without difficulty. This properly fit interface will be used with the E0470 device; and,
- B. E0601 pressure settings. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy and lower pressure settings of the E0601 were tried but failed to:
 - 1. Adequately control the symptoms of OSA; or,
 - 2. Improve sleep quality; or,
 - 3. Reduce the AHI/RDI to acceptable levels.

The re-evaluation must take place within the first 3 months of treatment; however, formal assessment of improvement cannot be documented before the 31st day. The re-evaluation must document both improvement in subjective symptoms of OSA and objective data related to adherence to PAP therapy.

Documentation of adherence to PAP therapy shall be accomplished through direct download or visual inspection of usage data with documentation provided in a written report format to be reviewed by the treating practitioner and included in the beneficiary's medical record. This information does not have to be submitted with the claim but must be available upon request. Many suppliers have created forms which have not been approved by CMS which they send to practitioners and ask them to complete. Even if the practitioner completes this type of form and puts it in his/her chart, this supplier-generated form is not a substitute for the comprehensive medical record as noted above. Suppliers are encouraged to help educate practitioners on the type of information that is needed to document a beneficiary's need for PAP therapy.

Proper use of modifiers is discussed below. Specific modifiers must be used and differ depending on whether or not the requirements outlined in the documentation section have been met.

INITIAL COVERAGE (FIRST THREE MONTHS):

On claims for the first through third months, suppliers must add a KX modifier to codes for PAP equipment (E0470 or E0601) and accessories only if all of the criteria in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related LCD ("Initial Coverage") have been met.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

On the fourth month's claim (and any month thereafter), the supplier must add a KX modifier to codes for PAP equipment (E0470 or E0601) and accessories only if both the "Initial Coverage" criteria and the "Continued Coverage" criteria in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related LCD have been met.

If the supplier does not obtain information from the practitioner that the beneficiary has demonstrated improvement in their OSA symptoms and is adhering to PAP therapy in time for submission of the fourth or succeeding months' claims, the supplier may still submit the claims, but a KX modifier must not be added.

If the supplier chooses to hold claims for the fourth and succeeding months pending receipt of information from the treating practitioner that the beneficiary received a clinical re-evaluation between the 31st and 91st day, had documented improvement in OSA symptoms and is adhering to PAP therapy, those claims may then be submitted with the KX modifier.

If the supplier chooses to hold claims for the fourth and succeeding month pending receipt of information from the treating practitioner but learns that the beneficiary did not receive a clinical re-evaluation between the 31st and 91st day but rather was re-evaluated at a later date and had documented improvement in OSA symptoms and is adhering to PAP therapy, those claims may then be submitted with the KX modifier but only for dates of service following the date of the clinical re-evaluation.

For a PAP device dispensed prior to November 1, 2008, if the initial coverage criteria in effect at the time were met and the criteria for coverage after the first 3 months that were in effect at the time were met, the KX modifier may be added to claim with dates of service on or after November 1, 2008 as long as the beneficiary continues to use the device.

BENEFICIARIES ENTERING MEDICARE:

For beneficiaries who received a PAP device prior to enrollment in fee for service (FFS) Medicare and are seeking Medicare coverage of either rental of the device, a replacement device or accessories, the supplier may add the KX modifier only if both of the criteria listed in the Coverage Indications, Limitations and/or Medical Necessity for Beneficiaries Entering Medicare section of the related LCD have been met.

The supplier may hold claims, pending confirmation that the above requirements are met, and then submit claims with the KX modifier beginning with the date of FFS Medicare enrollment.

CONCURRENT USE OF OXYGEN WITH PAP THERAPY

In the rare instance where beneficiaries require the simultaneous use of home oxygen therapy and a PAP device, documentation by the treating practitioner in the beneficiary's medical record must clearly demonstrate that the requirements for coverage outlined in the PAP LCD Coverage Indications, Limitations and/or Medical Necessity have been met. In addition, the beneficiary's medical record must also clearly demonstrate that the requirements for coverage outlined in the Oxygen and Oxygen Equipment LCD Coverage Indications, Limitations and/or Medical Necessity have been met. This information does not have to be submitted with the claim but must be available upon request.

Suppliers should refer to the Oxygen and Oxygen Equipment LCD and related Policy Article for

additional coverage, coding and documentation requirements.

MODIFIERS

GA, GZ, and KX MODIFIERS:

In all of the situations above describing use of the KX modifier, if all of the coverage criteria have not been met, the GA or GZ modifier must be added to a claim line for the PAP equipment and accessories. When there is an expectation of a reasonable and necessary denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claim lines billed without a GA, GZ or KX modifier will be rejected as missing information.

MISCELLANEOUS

Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

The order must include the type(s) of supplies ordered and the approximate quantity to be used per unit of time. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used.

The supplier must enter the diagnosis code for the PAP device on each claim submitted for PAP supplies.

Refer to the Supplier Manual for additional information on documentation requirements.

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

Related Policies

- Actigraphy
 - Home Cardiorespiratory Monitoring For Pediatrics
 - Obstructive Sleep Apnea and Snoring - Surgical Treatment
 - Diagnosis of Sleep Disorders
-

References

1. Somers VK, White DP, Amin R, et al. Sleep apnea and cardiovascular disease: an American Heart Association/American College Of Cardiology Foundation Scientific Statement from the American Heart Association Council for High Blood Pressure Research Professional Education Committee, Council on Clinical Cardiology, Stroke Council, and Council On Cardiovascular Nursing. In collaboration with the National Heart, Lung, and Blood Institute National Center on Sleep Disorders Research (National Institutes of Health). Circulation. Sep 2 2008;118(10):1080-1111. PMID 18725495

2. Kushida CA, Littner MR, Morgenthaler T, et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. *Sleep*. Apr 1 2005;28(4):499-521. PMID 16171294
3. Crook S, Sievi NA, Bloch KE, et al. Minimum important difference of the Epworth Sleepiness Scale in obstructive sleep apnoea: estimation from three randomised controlled trials. *Thorax*. Apr 2019; 74(4):390-396. PMID 30100576
4. Patil SP, Ayappa IA, Caples SM, et al. Treatment of Adult Obstructive Sleep Apnea With Positive Airway Pressure: An American Academy of Sleep Medicine Systematic Review, Meta-Analysis, and GRADE Assessment. *J Clin Sleep Med*. Feb 15 2019; 15(2): 301-334. PMID 30736888
5. Patil SP, Ayappa IA, Caples SM, et al. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. Feb 15 2019; 15(2): 335-343. PMID 30736887
6. Balk EM, Moorthy D, Obadan NO, et al. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32 (AHRQ Publication No. 11-EHC052-EF). Rockville, MD: Agency for Healthcare Research and Quality; 2011.
7. Berry RB, Parish JM, Hartse KM. The use of auto-titrating continuous positive airway pressure for treatment of adult obstructive sleep apnea. An American Academy of Sleep Medicine review. *Sleep*. Mar 15 2002; 25(2): 148-73. PMID 11902425
8. Littner M, Hirshkowitz M, Davila D, et al. Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome. An American Academy of Sleep Medicine report. *Sleep*. Mar 15 2002; 25(2): 143-7. PMID 11902424
9. Kushida CA, Morgenthaler TI, Littner MR, et al. Practice parameters for the treatment of snoring and Obstructive Sleep Apnea with oral appliances: an update for 2005. *Sleep*. Feb 2006; 29(2): 240-3. PMID 16494092
10. Morgenthaler TI, Aurora RN, Brown T, et al. Practice parameters for the use of autotitrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome: an update for 2007. An American Academy of Sleep Medicine report. *Sleep*. Jan 2008; 31(1): 141-7. PMID 18220088
11. Hussain SF, Love L, Burt H, et al. A randomized trial of auto-titrating CPAP and fixed CPAP in the treatment of obstructive sleep apnea-hypopnea. *Respir Med*. Apr 2004; 98(4): 330-3. PMID 15072173
12. Marrone O, Resta O, Salvaggio A, et al. Preference for fixed or automatic CPAP in patients with obstructive sleep apnea syndrome. *Sleep Med*. May 2004; 5(3): 247-51. PMID 15165530
13. Stammnitz A, Jerrentrup A, Penzel T, et al. Automatic CPAP titration with different self-setting devices in patients with obstructive sleep apnoea. *Eur Respir J*. Aug 2004; 24(2): 273-8. PMID 15332397
14. Yu J, Zhou Z, McEvoy RD, et al. Association of Positive Airway Pressure With Cardiovascular Events and Death in Adults With Sleep Apnea: A Systematic Review and Meta-analysis. *JAMA*. Jul 11 2017;318(2): 156-166. PMID 28697252
15. McEvoy RD, Antic NA, Heeley E, et al. CPAP for Prevention of Cardiovascular Events in Obstructive Sleep Apnea. *N Engl J Med*. Sep 08 2016; 375(10): 919-31. PMID 27571048
16. Lisan Q, Van Sloten T, Marques Vidal P, et al. Association of Positive Airway Pressure Prescription With Mortality in Patients With Obesity and Severe Obstructive Sleep Apnea: The Sleep Heart Health Study. *JAMA Otolaryngol Head Neck Surg*. Jun 01 2019; 145(6): 509-515. PMID 30973594

17. Fox N, Hirsch-Allen AJ, Goodfellow E, et al. The impact of a telemedicine monitoring system on positive airway pressure adherence in patients with obstructive sleep apnea: a randomized controlled trial. *Sleep*. Apr 01 2012; 35(4): 477-81. PMID 22467985
18. Mutter TC, Chateau D, Moffatt M, et al. A matched cohort study of postoperative outcomes in obstructive sleep apnea: could preoperative diagnosis and treatment prevent complications?. *Anesthesiology*. Oct 2014; 121(4): 707-18. PMID 25247853
19. Pattipati M, Gudavalli G, Zin M, et al. Continuous Positive Airway Pressure vs Mandibular Advancement Devices in the Treatment of Obstructive Sleep Apnea: An Updated Systematic Review and Meta-Analysis. *Cureus*. Jan 2022; 14(1): e21759. PMID 35251830
20. Ramar K, Dort LC, Katz SG, et al. Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015. *J Clin Sleep Med*. Jul 15 2015; 11(7): 773-827. PMID 26094920
21. Yu M, Ma Y, Han F, et al. Long-term efficacy of mandibular advancement devices in the treatment of adult obstructive sleep apnea: A systematic review and meta-analysis. *PLoS One*. 2023; 18(11): e0292832. PMID 38015938
22. Liao J, Shi Y, Gao X, et al. Efficacy of Oral Appliance for Mild, Moderate, and Severe Obstructive Sleep Apnea: A Meta-analysis. *Otolaryngol Head Neck Surg*. May 2024; 170(5): 1270-1279. PMID 38363016
23. Johal A, Haria P, Manek S, et al. Ready-made versus custom-made mandibular repositioning devices in sleep apnea: a randomized clinical trial. *J Clin Sleep Med*. Feb 15 2017; 13(2): 175-182. PMID 27784410
24. Bosschieter PFN, Uniken Venema JAM, Vonk PE, et al. Equal effect of a noncustom vs a custom mandibular advancement device in treatment of obstructive sleep apnea. *J Clin Sleep Med*. Sep 01 2022; 18(9): 2155-2165. PMID 35532113
25. Belkhode V, Godbole S, Nimonkar S, et al. Comparative evaluation of the efficacy of customized maxillary oral appliance with mandibular advancement appliance as a treatment modality for moderate obstructive sleep apnea patients-a randomized controlled trial. *Trials*. Feb 01 2023; 24(1): 73. PMID 36726182
26. Abreu AR, Stefanovski D, Patil SP, et al. Neuromuscular electrical stimulation for obstructive sleep apnoea: comparing adherence to active and sham therapy. *ERJ Open Res*. Nov 2023; 9(6). PMID 38152084
27. Wessolleck E, Bernd E, Dockter S, et al. Intraoral electrical muscle stimulation in the treatment of snoring. *Somnologie (Berl)*. 2018; 22(Suppl 2): 47-52. PMID 30595662
28. Kotecha B, Wong PY, Zhang H, et al. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. *Sleep Breath*. Dec 2021; 25(4): 2083-2090. PMID 33772397
29. Baptista PM, Martínez Ruiz de Apodaca P, Carrasco M, et al. Daytime Neuromuscular Electrical Therapy of Tongue Muscles in Improving Snoring in Individuals with Primary Snoring and Mild Obstructive Sleep Apnea. *J Clin Med*. Apr 27 2021; 10(9). PMID 33925376
30. Nokes B, Baptista PM, de Apodaca PMR, et al. Transoral awake state neuromuscular electrical stimulation therapy for mild obstructive sleep apnea. *Sleep Breath*. May 2023; 27(2): 527-534. PMID 35624401
31. Nokes B, Schmickl CN, Brena R, et al. The impact of daytime transoral neuromuscular stimulation on upper airway physiology - A mechanistic clinical investigation. *Physiol Rep*. Jun 2022; 10(12): e15360. PMID 35748091
32. Singh GD, Griffin T, Cress SE. Biomimetic oral appliance therapy in adults with severe obstructive sleep apnea. *J Sleep Disord Ther*. 2016; 5: 227.

33. Singh GD, Cress SE. Biomimetic oral appliance therapy in adults with mild to moderate obstructive sleep apnea using combined maxillo-mandibular correction. *J Sleep Disord Manag.* 2017;3(1):014.
34. Krakow B, Ulibarri V, Melendrez D, et al. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia individuals with sleep disordered breathing to positive airway pressure (PAP-NAP). *J Clin Sleep Med.* Jun 15 2008;4(3):212-222. PMID 18595433
35. Ulibarri VA, Krakow B, McIver ND. The PAP-NAP one decade later: individual risk factors, indications, and clinically relevant emotional and motivational influences on PAP use. *Sleep Breath.* Dec 2020; 24(4): 1427-1440. PMID 31898192
36. Riaz M, Certal V, Nigam G, et al. Nasal expiratory positive airway pressure devices (Provent) for OSA: a systematic review and meta-analysis. *Sleep Disord.* 2015;2015:734798. PMID 26798519
37. Berry RB, Kryger MH, Massie CA. A novel nasal expiratory positive airway pressure (EPAP) device for the treatment of obstructive sleep apnea: a randomized controlled trial. *Sleep.* Apr 2011;34(4):479-485. PMID 21461326
38. Kryger MH, Berry RB, Massie CA. Long-term use of a nasal expiratory positive airway pressure (EPAP) device as a treatment for obstructive sleep apnea (OSA). *J Clin Sleep Med.* Oct 15 2011;7(5):449-453B. PMID 22003339
39. Kureshi SA, Gallagher PR, McDonough JM, et al. Pilot study of nasal expiratory positive airway pressure devices for the treatment of childhood obstructive sleep apnea syndrome. *J Clin Sleep Med.* 2014;10(6):663-669. PMID 24932147
40. Sleeper G, Rashidi M, Strohl KP, et al. Comparison of expiratory pressures generated by four different EPAP devices in a laboratory bench setting. *Sleep Med.* 2022 May 13;96:87-92.
41. Lai V, Tong BK, Tran C, et al. Combination therapy with mandibular advancement and expiratory positive airway pressure valves reduces obstructive sleep apnea severity. *Sleep.* Aug 01 2019; 42(8). PMID 31180512
42. Srijithesh PR, Aghoram R, Goel A, et al. Positional therapy for obstructive sleep apnoea. *Cochrane Database Syst Rev.* May 01 2019; 5:CD010990. PMID 31041813
43. Eijsvogel MM, Ubbink R, Dekker J, et al. Sleep position trainer versus tennis ball technique in positional obstructive sleep apnea syndrome. *J Clin Sleep Med.* Jan 15 2015; 11(2): 139-47. PMID 25515276
44. de Ruiter MHT, Benoist LBL, de Vries N, et al. Durability of treatment effects of the Sleep Position Trainer versus oral appliance therapy in positional OSA: 12-month follow-up of a randomized controlled trial. *Sleep Breath.* May 2018; 22(2): 441-450. PMID 28913630
45. Berry RB, Uhles ML, Abaluck BK, et al. NightBalance Sleep Position Treatment Device Versus Auto-Adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea. *J Clin Sleep Med.* Jul 15 2019; 15(7): 947-956. PMID 31383231
46. van Maanen JP, de Vries N. Long-term effectiveness and compliance of positional therapy with the sleep position trainer in the treatment of positional obstructive sleep apnea syndrome. *Sleep.* Jul 01 2014; 37(7): 1209-15. PMID 25061249
47. Beyers J, Dieltjens M, Kastoer C, et al. Evaluation of a Trial Period With a Sleep Position Trainer in Individuals With Positional Sleep Apnea. *J Clin Sleep Med.* Apr 15 2018; 14(4): 575-583. PMID 29609712
48. Buyse B, Ciordas S, Hoet F, et al. Positional obstructive sleep apnoea: challenging findings in consecutive individuals treated with a vibrating position trainer. *Acta Clin Belg.* Dec 2019; 74(6): 405-413. PMID 30433857
49. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Treatment of obstructive sleep apnea. 2021 <https://www.entnet.org/resource/position-statement-treatment-of-obstructive-sleep-apnea>

50. Section on Pediatric Pulmonology - Subcommittee on Obstructive Sleep Apnea Syndrome. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. Apr 2002;109(4):704-712. PMID 11927718
51. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. Sep 2012; 130(3): 576-84. PMID 22926173
52. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. Jun 15 2009; 5(3): 263-76. PMID 19960649
53. Yeghiazarians Y, Jneid H, Tietjens JR, et al. Obstructive Sleep Apnea and Cardiovascular Disease: A Scientific Statement From the American Heart Association. *Circulation*. Jul 20 2021; 144(3): e56-e67. PMID 34148375
54. ASMBS Clinical Issues Committee. Peri-operative management of obstructive sleep apnea. *Surg Obes Relat Dis*. May-Jun 2012; 8(3): e27-32. PMID 22503595
55. Chowdhuri S, Quan SF, Almeida F, et al. An official American Thoracic Society research statement: impact of mild obstructive sleep apnea in adults. *Am J Respir Crit Care Med*. May 1 2016;193(9):e37-54. PMID 27128710
56. National Institute for Health and Care Excellence (NICE). Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s: NG202. Published August 20, 2021; <https://www.nice.org.uk/guidance/ng202/chapter/1-Obstructive-sleep-apnoeahypopnoea-syndrome#treatments-for-mild-osahs>.
57. National Institute for Health and Care Excellence (NICE). Daytime intraoral neuromuscular electrical tongue stimulation using a removable device for obstructive sleep apnoea [IPG760]. April 19, 2023. <https://www.nice.org.uk/guidance/ipg760/resources/daytime-intraoral-neuromuscular-electrical-tongue-stimulation-using-a-removable-device-for-obstructive-sleep-apnoea-pdf-1899876394571461>.
58. Bibbins-Domingo K, Grossman DC, et al. Screening for obstructive sleep apnea in adults: US Preventive Services Task Force Recommendation Statement. *JAMA*. Jan 24 2017;317(4):407-414. PMID 28118461
59. Jonas DE, Amick HR, Feltner C, et al. Screening for obstructive sleep apnea in adults: evidence report and systematic review for the US Preventive Services Task Force. *JAMA*. Jan 24 2017;317(4):415-433. PMID 28118460
60. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (240.4).2008; <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=226&ver=3>.
61. CGS Administrators, LLC, Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611; previous L28603), original effective date 10/01/15, revision effective date 08/08/2021.
62. American Academy of Sleep Medicine (AASM). AASM statement on Zepbound approval. Dec 23, 2024. <https://aasm.org/zepbound-approval-sleep-apnea-american-academy-sleep-medicine-statement>. Accessed September 17, 2025.
63. The Department of Veteran's Affairs and the Department of Defense (VA/DOD). VA/DOD Clinical Practice Guideline For The Management Of Chronic Insomnia Disorder And Obstructive Sleep Apnea. January, 2025. <https://www.healthquality.va.gov/guidelines/CD/insomnia/index.asp> Accessed September 17, 2025.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 18, 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

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

			(Tongue-Retaining Devices or Mandibular advancing/positioning devices. ○ Added Diagnosis of under OSA. ○ Updated the language in this bullet in bold to align with BCBSA: an AHI, RDI or REI of at least 5 events per hour in an individual with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke), AND ○ Under Exclusions: added The use of intraoral appliances that do not meet the above criteria are considered experimental/investigational for the treatment of OSA. Added for the treatment of OSA for clarification purposes under Palate and mandible expansion devices for the treatment of OSA are considered experimental/investigational. ○ Removed Positional therapy devices and added The use of sleep positioning trainers with vibration, and for the treatment of positional OSA for clarification purposes. ○ Policy Guidelines section moved to under Description/Background section. • Minor editorial refinements – updated patients to individuals. • Vendor: BCBSM/ BCN: Northwood. • References added. • Policy statements unchanged. • Title updated from Medical Management of Obstructive
--	--	--	---

			Sleep Apnea Syndrome to Medical Management of Obstructive Sleep Apnea Syndrome (Oral Appliances and Novel Therapies) Added K1001 under E/I as the policy discuss the use of sleep positioning trainers with vibration, and for the treatment of positional OSA are considered experimental/investigational. (ky)
9/1/23	6/13/23		- Added new code A7049 Expiratory positive airway pressure intranasal resistance valve EFD 4/1/23 per code update as E/I. - Added the device ULTepap™ by BRYGGS Medical, LLC for this code to the JUMP policy. - Removed NCD for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1) and LCD: Polysomnography and Other Sleep Studies (L36839) as this JUMP policy is for Medical Management of OSA Syndrome. - Going forward this policy will continue to be reviewed at April JUMP. - Vendor: Northwood. (ky)
7/1/24	4/16/24		- Routine maintenance - BCBSA updated their policy 8.01.67 – Medical Management of Obstructive Sleep Apnea Syndrome on July, 2023. - New HCPCS codes added E0492 E0493 E0530 EFD 1/1/24; E/I to replace deleted EFD 12/31/23 HCPCS codes K1028 K1029 K1001. - Title updated from Medical Management of Obstructive Sleep Apnea Syndrome (Oral Appliances and Novel Therapies) to Obstructive Sleep Apnea – Non-surgical Treatment. Per 4/18/23 JUMP recommendation, incorporated

			“Positive Pressure Airway Devices” Jump policy into this Jump policy. • Vendor: Northwood Post JUMP • Removed (age 1-17) from the statement below under Inclusions: ○ Clinically significant OSA in pediatric individuals is: • Upon further discussion, the HCPCS code K1037 was determined to be “Not a covered benefit - This is a convenience item, please reference the DME policy”. This code will not be placed on this policy and will only be on the DME policy. (ky)
7/1/25	4/15/25		• Routine maintenance • Based on BCBSA updates: the neuromuscular electrical tongue stimulation with the eXciteOSA device was moved from the novel device grouped indication to a new, standalone indication. • JUMP policy already had statement of daytime electrical stimulation of the tongue is considered E/I. • Minor Edits: Updated statement to reflect BCBSA's language: The use of neuromuscular electrical stimulation of the tongue is considered experimental/investigational for the treatment of OSA. • Added under the Inclusions section: 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. Note: this statement is already in the description section. • Added separate section for neuromuscular electric tongue stimulation under the rationale section. • Vendor: Northwood (ky)

1/1/26	10/21/25		• Annual review moved to Oct • Vendor: Northwood (slp) • Policy formatting updated • Removed treatment of “central apnea and mixed apnea” from the established medical policy statement
--------	----------	--	--

Next Review Date:

4th Qtr, 2026

Pre-Consolidation Medical Policy History

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

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: OBSTRUCTIVE SLEEP APNEA – NON-SURGICAL TREATMENT

I. Coverage Determination:

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

II. Administrative Guidelines:

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