Policy Number	**MED204.006**
Policy Effective Date	**09/15/2024**
Policy End Date	**12/31/2025**

Medical Management of Sleep Related Breathing Disorders

Table of Contents

Related Policies (if applicable)
MED204.005 Diagnosis of Obstructive Sleep Apnea Syndrome
MED201.049: Polysomnography for Non-Respiratory Sleep Disorders
SUR706.009 Sleep Related Breathing Disorders: Surgical Management

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

AUTO-ADJUSTING POSITIVE AIRWAY PRESSURE (APAP)

Titration of Pressure

Auto-adjusting positive airway pressure **may be considered medically necessary** for the titration of pressure in adults with clinically significant obstructive sleep apnea (OSA) defined as those who have:

- An Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (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 any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, history of stroke; OR
- If there is a significant change in weight or change in symptoms suggesting that continuous positive airway pressure (CPAP) should be re-titrated or possibly discontinued.

Treatment with APAP

Treatment with APAP **may be considered medically necessary** in adults when BOTH of the following criteria are met:

- Home or lab-based sleep study demonstrates ONE of the following:
  - AHI 15 or higher; OR
  - AHI 5 or higher with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, history of stroke;
- AND the individual has no contraindication to the use of APAP.

CONTINUOUS POSITIVE AIRWAY PRESSURE

CPAP **may be considered medically necessary** in individuals with clinically significant OSA.

Clinically significant OSA in adults is:

- An AHI, RDI, or REI ≥15, OR
- An AHI, RDI, or REI ≥5 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, history of 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

Bilevel Positive Airway Pressure for Obstructive Sleep Apnea

Bilevel positive airway pressure **may be considered medically necessary** in 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.

Bilevel Positive Airway Pressure (with or without back-up rate feature) for established Central Sleep Apnea (CSA)

Bilevel positive airway pressure with or without back-up rate feature **may be considered medically necessary** for individuals with established CSA diagnosed by an in-lab sleep study when BOTH of the following apply:

- Obstructive sleep apnea has been excluded or treated; and
- A titration study (split-night or whole-night) has demonstrated significant improvement of sleep-related hypoventilation adjusted to the settings that will be prescribed for home use (while breathing the individual's usual fraction of inspired oxygen [FiO2]).

NOTE 1: This medical policy only addresses bilevel positive airway pressure for obstructive sleep apnea and established central sleep apnea. This device may be used for other diagnoses including, but not limited to, restrictive thoracic disorders, severe chronic obstructive

pulmonary disease (COPD) and hypoventilation syndromes. These conditions are not addressed in this medical policy.

INTRAORAL APPLIANCES-ADULT INDIVIDUALS
Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices**) may be considered medically necessary** in adults with mild to moderate OSA who prefer oral appliances (OA) to CPAP, or who do not respond to CPAP, or are not appropriate candidates for CPAP, that meet ALL of the following conditions:

- The device is prescribed by a treating physician, and
- The device is custom-fitted by qualified dental personnel, **AND**

Either:

- MILD OSA: Apnea/hypopnea index (AHI), respiratory disturbance index (RDI) or respiratory event index (REI) 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, insomnia, hypertension, ischemic heart disease, or history of stroke, **OR**
- MODERATE OSA: AHI, RDI or REI greater than or equal to 15 events per hour, but less than or equal to 29 events per hour.

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) **may be considered medically necessary** in adult individuals with SEVERE OSA: AHI, RDI or REI greater than 30 events per hour who meet one of the following conditions:

- The patient is not able to tolerate a CPAP device; or
- The use of a CPAP device is contraindicated.

NOTE 2: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for patients with severe OSA, because oral appliances have been shown to be less efficacious in patients with severe OSA than in patients with mild-to-moderate OSA. Therefore, it is particularly important that patients with severe OSA have an initial trial of CPAP and that all reasonable attempts are made to continue treatment with CPAP, prior to the decision to switch to an oral appliance.

INTRAORAL APPLIANCES-PEDIATRIC INDIVIDUALS
Oral appliances **may be considered medically necessary** in the treatment of children with craniofacial anomalies with signs and symptoms of OSA.

Oral appliances **are considered experimental, investigational and/or unproven** for the treatment of OSA in children not meeting the above criteria.

The use of CPAP, bi-level positive airway pressure, APAP, and intraoral appliances that do not meet the above criteria **are considered experimental, investigational and/or unproven** for the treatment of OSA.

The use of an oral appliance therapy device with a compliance recorder (OAT-CR) (e.g., ProSomnus EVO® Sleep and Snore Device with Patient Monitoring) **is considered experimental, investigational and/or unproven** for the treatment of OSA.

Oral devices to prevent temporomandibular joint (TMJ) disorders **are considered experimental, investigational and/or unproven.**

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

The use of a sleep positioning trainer with vibration **is considered experimental, investigational and/or unproven** for the treatment of positional OSA.

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

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

Nasal expiratory positive airway pressure (EPAP) and oral pressure therapy devices **are considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

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

Obstructive Sleep Apnea

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

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

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

Cardiovascular and pulmonary systems can also be affected by OSA. (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 patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile collisions related to daytime sleepiness. It is estimated that about 7% of adults have moderate or severe OSA, 20% have mild OSA, and the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease. (1)

Diagnosis

Definitions of terms and scoring criteria for OSA are presented in Table 1. Obstructive sleep apnea is widely underdiagnosed with up to 95% of individuals with clinically significant OSA reporting no prior OSA diagnosis. Moreover, underdiagnosis is particularly prevalent in Black patients. The criterion standard for a diagnosis of sleep disorders is a polysomnogram performed in a sleep laboratory. (2) A standard polysomnogram includes electroencephalogram (EEG), submental electromyogram, and electrooculogram (to detect rapid eye movement sleep) for sleep staging. Polysomnography (PSG) also typically includes electrocardiography and monitoring of respiratory airflow and effort, snoring, oxygen desaturation, and sleep position. An attended study ensures that the electrodes and sensors are functioning adequately and do not dislodge during the night. In addition, an attendant is able to identify severe OSA in the first part of the night and titrate continuous positive airway pressure (CPAP) in the second part of the night, commonly known as a "split-night" study. If successful, this strategy eliminates the need for additional PSG for CPAP titration.

A variety of devices have also been developed specifically to evaluate OSA at home. They range from portable full PSG systems to single-channel oximeters. Available devices evaluate different

parameters, which may include oximetry, respiratory and cardiac monitoring, and sleep/wake activity, but most portable monitors do not record EEG activity.

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

- Habitual snoring;
- Observed apneas;
- Excessive daytime sleepiness;
- Body mass index (BMI) greater than 35 kg/m^2.

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

The STOP-BANG questionnaire, a method developed for non-sleep specialists, assesses the signs and symptoms of OSA (Snore, Tired, observed apnea, blood Pressure, BMI, Age, Neck, Gender), and has been shown to have 97% sensitivity and 96% negative predictive value (specificity, 33%) for the identification of individuals with severe OSA (Apnea/Hypopnea Index [AHI] >30 events per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is inadequate for the diagnosis of OSA. Therefore, a follow-up PSG or home sleep apnea test would still be required to confirm or exclude a diagnosis of OSA.

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% arterial oxygen desaturation (depending on criteria) or an arousal. • Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or an 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 increasing respiratory effort, terminating in an 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	• Adults: AHI or RDI of 5 to <15. • Children: AHI ≥1.0 to <5.
Moderate OSA	• AHI or RDI of 15 to < 30. • Children: AHI of ≥ 5 to <10.
Severe OSA	• Adults: AHI or RDI ≥30. • Children: AHI of ≥10.
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.
Positive airway pressure	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP.
PAP	Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation and for delivery of positive airway pressure.
PAP failure	Usually defined as an AHI >20 events per hour while using CPAP.
PAP intolerance	CPAP use for <4 hours per night for ≥5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA.

AHI: Apnea/hypopnea Index; APAP: auto-adjusting positive airway pressure; CPAP: continuous positive airway pressure; EEG: electroencephalogram; OSA: obstructive sleep apnea; PAP: positive airway

pressure; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal; UARS: upper airway resistance syndrome.

Treatment

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

ProSomnus snore device and Prosomnus EVO® Sleep and Snore Device with Patient Monitoring

The ProSomnus® EVO Sleep and Snore Device is an oral device, which improves the flow of air through the patient's pharyngeal space during sleep by repositioning the mandible. The device consists of maxillary and mandibular devices that when interfaced together reduce snoring and mild to moderate obstructive sleep apnea by holding the mandible forward during sleep, providing increased pharyngeal space. A micro-recorder is completely embedded in the ProSomnus® EVO Sleep and Snore Device with Patient Monitoring. The micro-recorder is a compliance sensor, which logs the time the device is worn. (53)

Specialist Training

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

Surgical management of OSA (i.e., uvulopalatopharyngoplasty, orthognathic surgery) is discussed in SUR706.009 Sleep Related Breathing Disorders: Surgical Management.

Central Sleep Apnea (CSA)

Rana and Sankari (2023) note that central sleep apnea (CSA) is different from obstructive sleep apnea, in which there is abnormal breathing due to upper airway obstruction. Patients may have abrupt awakenings accompanied by shortness of breath, insomnia, and excessive daytime sleepiness, along with difficulty concentrating and mood changes. CSA represents an array of sleep-disordered breathing (SDB) conditions due to the brief absence of ventilatory output during sleep. CSA manifests as a cyclical phenomenon/pattern during sleep; periods of apnea or hypopnea alternating with hyperpnea. (52) Rana and Sankari note that the prevalence of CSA is lower than obstructive sleep apnea but both conditions often coexist, and patients can exhibit features of both states. The authors note that the International Classification of Sleep Disorders – Third Edition (ICSD-3) had divided CSA syndromes into several categories based on distinct clinical and polysomnographic features:

1. Primary CSA,
2. CSA with Cheyne-Stokes beathing (CSB),
3. CSA due to a medical disorder without CSB,
4. CSA due to a periodic high-altitude breathing,
5. CSA due to a medication or substance,
6. Treatment-emergent CSA.

The goal standard for diagnosis is a sleep study called polysomnogram that measures breathing effort and airflow, vitals, and blood oxygen level during different stages of sleep. Treatment includes identifying underlying causes and treating any precipitating factors. Ideally, these patients need to be evaluated by a sleep physician.

Regulatory Status

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

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

Novel devices for OSA treatment are described in Table 2.

Table 2. Novel Devices for OSA Treatment

Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
Provent®	Ventus Medical	Nasal expiratory resistance valve.	K102404	OHP	2010
Winx™	Apnicure, Inc.	Nasal expiratory resistance valve.	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 patients with positional obstructive sleep	K180608	MYB	2018

		apnea from sleeping in the supine position.			
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
ProSomnus EVO® and Snore Device, ProSomnus EVO® Sleep and Snore Device with Patient Monitoring	ProSomnus Sleep Technologies, Inc.	A mandibular advancement device/appliance for the treatment of snoring and mild to moderate obstructive sleep apnea (OSA) in adults. A micro-recorder embedded in the device is intended to measure patient compliance to oral device/appliance therapy in combination with the systems docking station.	K202529	LRK LQZ PLC	2020

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

On November 20, 2020 ProSomnus EVO® and Snore Device, and Prosomnus EVO® Sleep and Snore Device with Patient Monitoring was cleared for marketing through the FDA 510(k) process. The ProSomnus EVO® and Snore Device is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults. Optionally, if the DentiTrac micro-recorder is completely embedded in the Prosomnus EVO® Sleep and Snore Device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the DentiTrac System. (53)

Rationale

This medical policy was created in August 2022 with a search of the PubMed database. The most recent literature update was performed through April 30, 2024.

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Positive Airway Pressure Devices

Clinical Context and Therapy Purpose

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

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

Populations

The relevant population of interest is individuals with OSA.

Interventions

The therapy being considered is various types of PAP therapy (i.e., fixed continuous positive airway pressure [CPAP], bilevel PAP, or auto-adjusting positive airway pressure [APAP]) during sleep.

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

Comparators

The following therapy is currently being used to make decisions about the treatment of OSA: weight loss, position therapy, and CPAP or its variants. The major limitation of PAP therapy is poor patient compliance due to the need to wear a face or nasal mask.

Outcomes

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

Table 3. Health Outcome Measures Relevant to OSA

Outcome	Measure	Description	Clinically Meaningful Difference (If Known)
Change in AHI	AHI	Mean change in AHI from baseline to posttreatment	Change from severe-to moderate or mild OSA
AHI success	Percentage of patients achieving success	Studies may use different definitions of success, but the most common for AHI success is the Sher criteria	• Sher criteria include a decrease in AHI of ≥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 patients how likely they are to fall asleep in 8 different situations (e.g.,	An ESS of ≥10 is considered excessively sleepy. A decrease of 2 points is considered the MID. (3)

		watching television, sitting quietly in a car, or sitting and talking to someone)	
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.

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

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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 patients. PAP initiation in the home had equivalent effects on patient outcomes compared to in-laboratory titration, and there were no clinically significant differences in patient outcomes

with the use of auto-adjusting or bilevel PAP compared with standard continuous PAP. Adherence to PAP was improved with the use of educational, behavioral, troubleshooting, and telemonitoring interventions.

Balk et al. (2011) conducted a comparative effectiveness review for the Agency for Healthcare Research and Quality (AHRQ) on the diagnosis and treatment of OSA in adults. The review concluded that the strength of evidence for CPAP for OSA was moderate based on the large magnitude of effect on the intermediate outcomes of the AHI, ESS score, and arousal index, even though there was weak evidence demonstrating an effect of CPAP on clinical outcomes. (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 patients with OSA. There was moderate evidence that CPAP is superior to mandibular advancement devices (MADs) in improving sleep study measures.

Evidence-based guidelines from the AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals. (7, 8, 9, 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 patients with sleep apnea. There were 356 major adverse cardiovascular events and 613 deaths observed during follow-up (range, 6-57 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 patients from the Sleep Heart Health Study who had obesity and severe OSA. (16) For the 81 patients who were prescribed PAP therapy, the propensity-matched hazard ratio for all-cause mortality was 0.58 (95% CI, 0.35 to 0.96) compared to matched patients who did not receive a prescription for PAP. Survival curves indicated that the difference in mortality appeared 6 to 7 years after initiation of PAP. Exploratory analysis indicated that PAP might also be associated with a lower risk of cardiovascular mortality.

Randomized Controlled Trials

Monitoring of APAP use by daily transmission to a web-based database and review by a research coordinator has been shown to improve compliance to PAP therapy (191 min/day vs. 105 min/day). (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 patient if any of the following were present: mask leak greater than 40 L/min for more than 30% of the night, less than 4 hours of use for 2 consecutive nights, machine-measured AHI of more than 10 events per hour, and 90th percentile of pressure greater than 16 cm 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 patients with OSA who had been diagnosed prior to surgery (2640 surgeries), those not diagnosed until up to 5 years after surgery (1571 surgeries), and 16277 surgeries for patients without a diagnosis of OSA over 21 years of available data. (18) In multivariate analysis, the risk of respiratory complications was increased for both diagnosed and undiagnosed OSA patients compared with controls (odds ratio, 2.08; p<.001). The risk of cardiovascular complications, primarily cardiac arrest and shock, was higher in OSA patients not diagnosed until after surgery (relative risk, 2.20; 95% CI, 1.16 to 4.17; p=.02), but not in those diagnosed prior to surgery (relative risk, 0.75; 95% CI, 0.43 to 1.28; p=.29); the difference between groups was statistically significant (p=.009). There was a significant trend toward a higher risk with increasing OSA severity. Study limitations included the inability to determine whether CPAP was used perioperatively, and, because body mass index could not be determined, potential confounding from the close association between obesity and OSA.

Section Summary: Positive Airway Pressure Devices

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

Oral Appliances

Clinical Context and Therapy Purpose

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

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

Populations

The relevant population of interest is individuals with OSA.

Interventions
The therapy being considered is oral appliances during sleep.

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

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

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

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

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

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
In the AHRQ report (2011) on the diagnosis and treatment of OSA in adults, the strength of the evidence that MADs improve sleep apnea signs and symptoms was rated moderate. (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 AASM 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 first-line therapy for treating OSA. The baseline demographics in regards to racial and ethnic diversity were not reported in either review.

Ready-made Versus Custom-made Mandibular Advancement Devices

Randomized Controlled Trials

Johal et al. (2017) reported on a randomized crossover trial of ready-made versus custom-made MADs. (21) Twenty-five patients with mild-to-moderate OSA (mean AHI, 13.3 events/hour; range, 10.9 to 25 events/hour) were randomized to a 3-month trial of a ready-made or a custom-made device, with a 2-week washout between treatments. An overnight home sleep apnea test was performed at baseline and on the last night of the 3-month trial period. Patients used the custom-made device for more nights per week (7 vs. 3, p=.004) and hours per night (5 vs. 3, p=.006) than the ready-made device. Treatment response (AHI <5 events per hour) was obtained in 64% of patients during use of the custom-made device phase compared with a 24% response rate using the ready-made device (p<.001). Treatment failure (<50% reduction in AHI) was more frequent with the ready-made device (36%) than with the custom device (4%), while an ESS score of at least 10 was more frequent during the ready-made phase (66%) than with the custom-made phase (33%). An improvement in the QOL was observed only during the custom-made device phase.

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

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

Section Summary: Oral Appliances

Custom oral appliances, which may include mandibular repositioning or tongue-retaining devices, are an accepted therapy for mild-to-moderate OSA. A 2015 and 2022 meta-analysis demonstrated the efficacy of oral appliances for measures of OSA, but they were generally less effective than CPAP. Conflicting data exists on if custom-made MADs demonstrate superior impact on symptoms and QOL outcomes compared to ready-made MADS, based on available RCTs.

Novel Obstructive Sleep Apnea Treatments

Clinical Context and Therapy Purpose

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

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

Populations

The relevant population is individuals with OSA.

Interventions

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

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

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

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

Other devices being marketed for the treatment of OSA are Provent and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA. Oral pressure therapy provides light negative pressure to the oral cavity by using a flexible mouthpiece connected to a bedside console that delivers negative pressure. This device is proposed to increase the size of the retropalatal airway by pulling the soft palate forward and stabilizing the base of the tongue.

Comparators

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

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

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

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

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Palate and Mandible Expansion
Case Series
Singh et al. (2016) reported on a series of 15 consecutive patients with severe sleep apnea who were treated with a DNA Appliance or mRNA Appliance. (24) All patients had failed to comply with CPAP. Pre- and post-treatment AHI was assessed in a home sleep apnea test without the oral appliance. AHI decreased from a mean of 45.9 events per hour to 16.5 ($p<.01$) after a mean of 9.7 months of treatment.

Singh et al. (2016) and Cress (2017) reported on a series of 19 patients who had mild-to-moderate OSA who were treated with a DNA or mRNA Appliance. (25) Only patients who complied with oral appliance wear were included in the study. The mean AHI was reduced from 12.85 to 6.2 events per hour ($p<.001$) with the appliance, while the Oxygen Desaturation 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 polysomnography (PSG), uncertain blinding of the physician evaluating the sleep study, the small number of patients studied, lack of intention-to-treat (ITT) analysis, and lack of long-term follow-up.

Daytime Sleep Study (PAP-NAP)

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

Nonrandomized Comparative Study

Krakow et al. (2008) reported on the use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP. (26) Patients had been referred by psychiatrists or primary care physicians for unspecified insomnia conditions, insomnia due to a mental disorder, or hypnotic dependence. Nearly all patients had anxiety, fear, and/or resistance regarding PAP therapy or the diagnosis of OSA. Thirty-nine patients who would not complete a titration protocol (full-night or split-night) were offered a daytime procedure (PAP-NAP) prior to night-time titration. The PAP-NAP protocol had 5 components: pretest instructions to maximize chances for daytime napping; introduction of PAP therapy addressing barriers to use; type 3 monitoring hookup (10 channels without electroencephalography (EEG) leads); PAP therapy during 1 to 2 hours in bed in which the patient had the opportunity to fall asleep with the mask in place; and post-test follow-up. Thirty-five of 39 nap-tested patients subsequently scheduled and completed an overnight titration or split-night study with full PSG. The effect of the PAP-NAP intervention on compliance was compared with historical controls (n=38) who had insomnia, mental health conditions, and OSA with resistance to CPAP who completed titration. A prescription for PAP therapy was filled by 85% of the PAP-NAP group compared with 35% of controls. Regular use during a 30-day period was recorded by the PAP device in 67% of the intervention group and in 23% of controls. Adherence, defined as at least 5 days a week with an average of at least 4 hours a day, was 56% in the PAP-NAP group and 17% in controls.

Retrospective Cohort Study

The same group of investigators (Ulibarri et al., 2020) conducted a retrospective chart review of 139 patients who were diagnosed with OSA or upper airway resistance syndrome between 2011 and 2016 and had initially refused titration of PAP but accepted a trial of PAP with a PAP-NAP. (27) The most common risk factors for initial PAP rejection were depression, insomnia, claustrophobia, and trauma exposure, while the most common indications for PAP-NAP were general reluctance, anxiety, and claustrophobia. The procedure averaged about 3 hours, which included 83 + 30 min of coaching and 107 + 57 min napping; 99% of patients experienced expiratory pressure intolerance and a majority preferred an alternative PAP mode for the nap period. Use at follow-up was determined by renewal request for PAP supplies, retitration, clinic appointment, or other contacts with staff. The duration of use is unclear from the report, but at the time of follow-up 71% of patients who had initially refused PAP were considered users and 29% were non-users.

<u>Nasal Expiratory Positive Airway Pressure</u>

Systematic Reviews

A systematic review by Riaz et al. (2015) identified 18 studies (N=920) that had data on pre-and postnasal EPAP. (28) Study designs included 10 conference papers and 8 publications (case series, cohort studies, RCTs). For patients included in the meta-analysis (n=345), AHI decreased from 27.32 to 12.78 events per hour (p<.001). For 359 patients, ESS score modestly improved from 9.9 to 7.4 (p<.001). Data from the Berry et al. (2011) RCT (described below) were not

included in this meta-analysis because mean data were not reported. Response to the nasal EPAP was variable and inconsistent, and there were no clear characteristics (demographic factors, medical history, and/or physical exam finding) that predicted a favorable response.

Randomized Controlled Trials

Berry et al. (2011) reported on an industry-sponsored multicenter, double-blind, randomized sham-controlled trial of EPAP. (29) Two hundred fifty patients with OSA and an AHI of 10 or more events per hour were randomized to nasal EPAP (n=127) or to a sham device (n=123) for 3 months. A PSG was performed on 2 nights (device-on, device-off, in random order) at week 1 (92% follow-up) and after 3 months of treatment (78% follow-up). EPAP reduced median AHI from 13.8 to 5.0 events per hour (-52.7%) at week 1 and from 14.4 to 5.6 events per hour (-42.7%) at 3 months. This reduction in AHI in the treatment group was significantly greater (-7.3% at week 1, -10.1% at 3 months) than in the sham group. Over 3 months, the decrease in ESS score was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1-point difference in ESS score is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of 5 or more events per hour on the device-off PSG night. The oxygenation results (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 patients in the EPAP group and by 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing due to adverse events. Overall, the validity of these results was limited by the high dropout rate and uncertainty of the clinical significance of the results. Furthermore, the trial did not report the racial/ethnic composition of enrolled patients and enrolled mostly men.

Kryger et al. (2011), in an open-label extension of the randomized study by Berry et al. (2011), evaluated the 12-month safety and durability of the treatment response in patients who had an initially favorable response to EPAP. (30) Included were 41 (32%) of the 127 patients in the EPAP arm of the study who used the device for an average of at least 4 hours per night on at least 5 nights a week during months 1 and 2 and had at least a 50% reduction in AHI, or reduction to less than 10 events per hour, compared with the device-off PSG. Of the 51 (40%) of 127 eligible patients, 41 enrolled in the extension study, and 34 (27%) of 127 were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events per hour; the percentage of patients who met criteria for success was not reported. The arousal index was modestly decreased (from 23.9 to 19.0). After 12 months of treatment, the ESS score decreased from 11.1 to 6.0. The median percentage of reported nights used (entire night) was 89.3%. Device-related adverse events were reported by 42% of patients, most frequently difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study was limited by its inclusion only of responders and by the potential for a placebo effect on the ESS score. However, the data suggested that some patients might have responded to this device, and the patient compliance data might indicate a positive effect on

daytime sleepiness that leads to continued use of the device in about 25% of patients. Additional controlled studies are needed to distinguish between these alternatives.

Kureshi et al. (2014) reported on a small (N=14) double-blind, pilot, crossover RCT of EPAP in children to evaluate efficacy and compliance with this new treatment. (31) PSG with EPAP or a placebo device showed a significant mean improvement in Obstructive Apnea Index with EPAP (0.6 vs. 4.2, p=.01), but responses varied (3 did not improve, 2 worsened). No other measures were statistically significant in this trial. For responders who used the devices at home for 30 days, adherence was 83% of nights. ESS scores improved from 11 to 7 (p=.031) and Obstructive Sleep Apnea-18 questionnaire scores improved from 50 to 39 (p=.028). Other outcome measures did not improve significantly.

Oral and OroNasal Pressure Therapy

Randomized Controlled Trials

Lai et al. (2019) reported a study with 22 patients with OSA who were incomplete responders to an oral appliance (AHI > 5). (32) They were assessed with the oral appliance plus either an oral or an oronasal EPAP. Both the oral and oral/nasal devices were studied in the same night (split night PSG); the order of the EPAP devices was randomized. Power analysis indicated that 20 participants would be sufficient to detect an AHI difference of 7 between conditions. The trial did not report the racial/ethnic composition of enrolled patients and enrolled mostly men. Results demonstrated that 5 patients (23%) had at least a 50% reduction in total AHI with the oral EPAP compared to the oral appliance alone, while 10 patients (45%) had a 50% reduction in AHI with the combined oral and nasal EPAP valves. Neither of these was statistically significant. Only 2 patients (9%) achieved an AHI of less than 5 with the oral EPAP device compared to 9 (41%) with the combined oral and nasal valves. However, sleep efficiency was disrupted with the oronasal EPAP valves.

eXciteOSA

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

Prospective Cohort Studies

Two prospective, single-arm studies were identified. Both instructed participants to use the device for 20 min daily for 6 weeks. Objective sleep parameters were measured by a Watch-PAT and use was tracked by the accompanying smartphone app. The time snoring greater than 40 dB (all snoring) was a primary outcome. Subjective decrease in snoring by the bed partner was measured by a Visual Analogue Scale (VAS), and the ESS and the Pittsburg 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. (33) Patients with a body mass index (BMI) greater than 35 and AHI greater than 15 were excluded. For the 70 patients who completed the study, snoring time measured by the Watch-PAT decreased by 48% and bed partners reported an average reduction in snoring of 40%. The mean AHI decreased from 5.94 to 5.37 events per hour. The PSQI improved by

approximately 1 point for both the participants (7.03 [standard deviation (SD), 3.13] to 5.92 [SD, 2.83], p=.004) and bed partners (7.35 [SD, 2.76] to 6.33 [SD, 2.80], p=.029). In the 38 patients with mild OSA, AHI was reduced from 9.8 to 4.7 events/hour, and the ESS improved from 9.0 to 5.1 (p<.001). Compliance with the protocol as measured by the app ranged from 59.5% to 95.2% (mean utilization 83.3%).

In a study by Baptista et al. (2021), eXciteOSA was administered to 125 patients with a complaint of snoring and an AHI less than 15 (no more than mild OSA), 50 participants had an AHI of less than 5 and were considered primary snorers. (34) Only 1 participant withdrew due to inability to tolerate the treatment (gag reflex), and 115 participants completed the trial (92%). The mean reduction in the proportion of time with moderate or greater snoring decreased from 30.41% to 17.87% (41% reduction, p<.001). Bed-partner-reported snoring decreased from 6.1 to 3.7 (p<.001). ESS improved from 8.4 to 5.8 and the PSQI improved for both the participants (7.16 to 5.75; 95% CI, 0.89 to 1.92; p <.001) and bed partners (6.87 to 5.94; 95% CI, 0.15 to 1.68; p =.02). The AHI was reduced from 6.85 to 5.01 (p<.001), a difference that is not clinically significant.

NightBalance Sleep Position Trainer

Systematic Review

For some patients, apneic events occur predominantly when the individual is supine. Sleep position trainers for individuals with positional OSA are intended to reduce time on the back and can range from supine vibration alarm devices to tennis balls sewn into the back of night wear. A Cochrane review by Srijithesh et al. (2019) evaluated positional therapy for OSA. (35) The meta-analysis included 3 crossover studies with a vibration alarm and 5 with specially designed pillows or semi-rigid backpacks. The review found low to moderate evidence that CPAP was more effective than positional therapy in improving AHI (n=72), but positional therapy was more effective than no treatment for improving outcomes (n=251) and may have better adherence than CPAP. All of the studies were short-term and the long-term effect was uncertain.

Randomized Controlled Trials

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

Eijsvogel et al. (2015) compared the first generation sleep position trainer to "the tennis ball technique" with commercially available air pillows on the back in 55 participants. (36) Both devices reduced supine position by a median of 100% and reduced the median supine AHI to 0 events/hour during the 1-month sleep study. There were no significant differences between the groups for the ESS, VAS, and sleep-related QOL data. Objective compliance data for the entire month showed that the median hours used per night was numerically higher but did not achieve statistical significance due to variability (6.5 vs. 4.5; p=.078). There were significant

increases in the percentage of patients who used the device every day (51.7% vs. 15.4%, p=.005) and in effective compliance, measured by use for at least 4 hours per night on at least 5 days per week (75.9% vs. 42.3%, p=.011). Compliance in both groups decreased over the month of the study. Continued use after the month trial was not evaluated, and the clinical significance of an increase in compliance without a difference in sleepiness or quality of life is uncertain.

de Ruiter et al. (2018) evaluated 12-month efficacy of the NightBalance Sleep Position Trainer compared to oral appliance therapy in a multicenter randomized trial of participants with positional OSA. (37) This was a follow-up to a previously published 3-month study. There were no significant differences between the 2 groups in AHI, ESS, FOSQ, or the average hours of use per night. However, 41% of the participants dropped out of the study by the 12-month follow-up due to adverse events or lack of efficacy, and the results in the publication represent only those individuals who remained in the study. Sensitivity analysis with ITT was reported in a supplement, and in the worst-case scenario, AHI decreased by 1 with NightBalance and by 5.5 with the oral appliance. With ITT and last observation carried forward, the average hours of use per night decreased to 3.1 for NightBalance and 2.7 for the oral appliance (p=.522).

Berry et al. (2019) compared the NightBalance Sleep Position Trainer to APAP in a 6-week randomized crossover trial in treatment naive patients (N=117) with exclusive positional OSA. (38) The investigators selected a non-inferiority margin of 5 events/hour for the AHI endpoint and 30 minutes for adherence. The sleep position trainer achieved non-inferiority with a difference of 3.58 events/hour. APAP was more effective than the Sleep Position Trainer in terms of the AHI (p<.001), but adherence was better with NightBalance (p<.001). There were no significant differences between the treatments for total sleep time, sleep efficiency, sleep latency, wake after sleep onset, or the duration of sleep stages. The ESS was statistically better in the APAP phase, although this did not achieve clinical significance. Post-hoc analysis of participants who had a baseline ESS score of greater than 10 showed that while both treatments improved the ESS, APAP was more effective (final ESS: 9.5 vs. 11; p<.001). Patients reported that the NightBalance device was easier to use and more comfortable and would choose this device, but thought that APAP was more effective in treating sleep apnea.

Table 4. Summary of Key RCT Characteristics

Study; Trial	Coun-tries	Sites	Design	Participants	Interventions	
					Active	**Comparator**
Eijsvogel et el. (2015) (36)	EU		Randomized parallel arm	55 patients with mild to moderate symptomatic POSA who had been referred to a tertiary care center	4 weeks with the first generation NightBalance Sleep Position Trainer (n=29)	4 weeks with commercially available inflated airbags on the back (n=26)

de Ruiter et al. (2018) (37)	EU	2	Randomized parallel arm	99 patients with mild to moderate POSA, defined as AHI > 2times nonsupine AHI and total AHI < 15 events/hour	12 mo follow-up with NightBalance Sleep Position Trainer (n=48, 29 completed)	12 mo follow-up with OAT with an imbedded microchip to monitor usage (n=51, 29 completed)
Berry et al. (2019) (38) (POSAtive)	US	11	Randomized crossover	117 treatment-naïve patients with exclusive POSA, defined as a supine AHI > 2 times nonsupine AHI and a nonsupine AHI < 10 events/hour; total AHI was at least 15 events/hour (moderate to severe OSA)	6 weeks with the NightBalance Sleep Position Trainer	6 weeks with APAP

AHI: apnea/hypopnea index; APAP: auto-adjusting positive airway pressure; EU: European Union; OAT: oral appliance therapy; mo: months; OSA: obstructive sleep apnea; POSA: positional obstructive sleep apnea; RCT: randomized controlled trial; US: United States.

Table 5. Summary of Key RCT Results

Study	**AHI (SD)**	**Adherence (SD)**	**ESS (SD)**	**QOL (SD)**
Eijsvogel et el. (2015) (36)		***Hours per Night (SD)***		***QSQ (SD)***
N	48	55	48	48
NightBalance	median 3.9 (min 0.4 to max 30.8)	median 6.5 (min 5.5 to max 7.2)	6.0 ± 3.6	5.4 ± 1.2
TBT	median 5.8 (min 0.2 to max 23.1)	median 4.5 (min 1.1 to max 7.0)	7.8 ± 4.3	4.8 ± 1.3
p		.078		
de Ruiter et al. (2018) (37)	***12 mo follow-up***	***Hours per Night (SD)***		***FOSQ (SD)***
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) (38) (POSAtive)		***Minutes per Night***		
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; QOL: quality of life; QSQ: Quebec Sleep Questionnaire; RCT: randomized controlled trial; SD: standard deviation; TBT: tennis ball technique (airbags).

Table 6. Study Relevance Limitations

Study	Population [a]	Intervention [b]	Compar-ator [c]	Out-comes [d]	Duration of Follow-up [e]
Eijsvogel et el. (2015) (36)	3, 5. Not all patients would have qualified for treatment. The mean score on the Epworth Sleepiness Score was <10. 5. Racial/ethnic diversity of enrolled patients is not reported.	4. This was a first generation device.			1. There was no long-term follow-up after the 4 week intervention.
de Ruiter et al. (2018) (37)	5. Racial/ethnic diversity of enrolled patients is not reported.				
Berry et al. (2019) (38) (POSAtive)	5. Racial/ethnic diversity of enrolled patients is not reported.				1. There was no long-term follow-up after the 6 week cross-over phases.

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

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

[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 Complete-ness [d]	Power [e]	Statistical [f]
Eijsvogel et el. (2015) (36)	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) (37)	3. Allocation concealment unclear	1, 2. Participants could not be blinded to treatment assignment.	2. Patients lost to follow-up were not counted as treatment failures in the primary analysis.	1, 2. High loss to follow-up; 59% of patients completed the study.		
Berry et al. (2019) (38) (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 literature 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 patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Observational Studies

Van Maanen and de Vries (2014) conducted a prospective study in patients with mild to moderate positional OSA. (39) There were 145 patients who were asked to use the Sleep Position Trainer for 6 months with the option to keep the device at the end of the study. However, the data could not be retrieved in 39 patients, leaving 106 with objective data. The time spent supine decreased from 21% at baseline to 3% in the 53 participants (36%) who provided objective measurements at 6 months. Subjective measures (median ESS 11 to 8; PSQI 8 to 6; and FOSQ 87 to 103) were significantly improved compared to baseline, but only 66 participants out of the 145 (45%) completed the questionnaires. Analysis was per protocol rather than intent-to-treat, raising questions about the validity of the results. Objective Sleep Position Trainer compliance, defined as more than 4 hours of usage per night as an average over 168 nights, was 64.4%; regular use, defined as at least 4 hours per night over at least 5 nights, was 71.2% averaged over the trial period. Objective use of the device for at least 1 hour per night decreased from 106 patients at the start of the study to less than 60 by 6 months. It is uncertain whether the number of patients using the device would be as high as this outside of a trial.

Beyers et al. (2018) invited patients to participate in a 1-month trial of the sleep position trainer as part of a standard clinical pathway at a university hospital. (40) In order to qualify for the trial, patients were required to have an overall AHI of > 5 events/hour, a supine AHI at least twice as high as the non-supine AHI, and 10% to 90% of total sleep time spent in the supine position. Out of 101 patients, 79 (78%) completed the 28-day trial period. There were 45 responders who had an overall reduction in Respiratory Event Index (REI) from 11.3 to 3.4 and a reduction in supine REI from 28.9 to 2.3. For the 44 patients (43% of 101) who decided to purchase the device, 27 (27% of total) were considered responders. Reasons for not purchasing the device included persistent daytime sleepiness, intolerance to the vibrations, and preference for other treatment options. Due to the relatively low percentage of patients who responded and chose to purchase the device, the investigators recommended a trial period. Treatment success over longer than the 1 month trial period was not evaluated. Similar findings were reported in a separate clinical study of 51 consecutive patients with positional OSA who had a 1-month trial of the NightBalance device. (41) About half of patients (n=27) were considered

adherent during the trial, and half of those (n=13) wanted to purchase the device. Ten patients had a higher response to the vibrations and were considered cured.

Section Summary: Novel Obstructive Sleep Apnea Treatments

The evidence on palate and mandible expansion devices includes a few small case series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on the PAP-NAP includes 1 comparative trial with historical controls and a retrospective cohort study of patients who were resistant to CPAP titration. These studies do not provide sufficient evidence to form conclusions on the efficacy of this approach in improving compliance with CPAP. The patient population in the comparative study was highly selected and the behavioral intervention may be dependent on the specific clinicians providing treatment. In addition, historical controls were used, and they were not well-matched to the study population. For these reasons, the internal validity and generalizability of the results are uncertain. The evidence on nasal EPAP devices in patients with OSA has been reported in smaller RCTs, an industry-sponsored RCT, and a systematic review that did not include the industry-sponsored RCT. The main finding of the industry-sponsored RCT was a decrease in AHI with a minor impact on oxygenation and ESS scores. An oral EPAP device did not have significant benefit when added to an oral appliance in a small RCT.

No controlled trials on eXciteOSA were identified. The evidence includes 2 prospective, single-arm studies in patients with primary snoring or mild OSA. The available evidence suggests that when used for 20 min per day over 6 weeks, the treatment may reduce snoring. In the overall population, the effects on AHI were not clinically significant. For the subgroup of patients with mild OSA, the improvement in AHI in these uncontrolled trials remained modest. With a mean ESS of less than10, this group of patients might not be considered symptomatic. Controlled studies are needed to evaluate whether patients who meet the criteria for treatable OSA improve and whether individuals would continue use after the 6-week trial period. The evidence on the NightBalance Sleep Positioning Trainer Includes RCTs and single-arm studies. The RCTs suggest that the device may be as effective as oral appliances and more comfortable than PAP in patients with positional OSA. However, the studies are limited by a high dropout rate and short follow-up. A 6-month prospective study found that 64% of patients used the sleep position trainer for more than 4 hours per night, but another observational study found that only about one-quarter of patients may be both able to tolerate the device and have a reduction in supine AHI in the short-term. Further study is needed to evaluate who may receive benefit and continue utilization after the trial period.

Oral Appliance Therapy Device with Compliance Recorder

Hu and Liptak (2018) reported on a study to evaluate the clinical feasibility of a novel oral appliance therapy device with a compliance recorder (OAT-CR) and report the objectively collected data. (54) This is the first study to report on a commercially available OAT-CR. In this single-center pilot study, 8 consecutive patients with diagnosed obstructive sleep apnea who were treated with standard of care oral appliance therapy were fitted with a new OAT-CR. The objectively recorded compliance data were acquired at follow-up appointments. Compliance data were acquired for each patient during follow-up appointments by placing the device on

the compliance recorder base station, which transferred the data from the chip to an online report provided by the chip manufacturer. The report tracked nightly compliance data, as well as aggregate performance data throughout the treatment period. Results noted by the authors included that the OAT-CR device worked as intended for eight of eight patients. Compliance data were recorded for a total of 366 nights, a mean of 45.8 ± 26.3 nights per study participant. The objectively recorded compliance rate in this study was 87.9% ± 20.4%. Mean usage was 7.4 ± 1.4 hours per night, based on the objectively recorded compliance data. The authors concluded that based on the results for this pilot study, the new OAT-CR is an option for clinical situations where objective compliance tracking is required or preferred. Objectively recorded compliance and mean nightly usage data in this study affirm oral appliance therapy compliance rates reported in previous studies.

Stern et al. (2021) reported on the EFFECTS study that aimed to evaluate the effectiveness of a new mandibular advancement device (MAD) (Prosomnus® [IA] Sleep Device, Prosomnus Sleep Technologies, Pleasanton CA) fitted with a compliance tracker as a first-line treatment in a population of patients with mild to severe OSA. (55) Treatment effectiveness was measured using pre- and post-treatment home sleep testing (HST) and validated sleep and QOL questionnaires. Mean disease alleviation (MDA) was calculated to compare the treatment effectiveness of MAD to historical continuous positive airway pressure (CPAP) effectiveness data. Patients who presented to a specialized sleep apnea diagnostic and treatment center and were subsequently diagnosed with OSA and chose an oral appliance as therapy over CPAP as first-line treatment were offered participation in the trial. Adult subjects were selected from all potential patients when the AHI was equal to or less than 50, with the exclusion of pregnant women (AHI less than 5 is normal, 5-14.9 is mild, 15-29.9 is moderate, and 30 and above is considered severe). Within the study group, patients' age ranged from 18-75. Initially, 42 subjects consented to participate in the study but only 28 subjects followed through to obtain their MAD and complete post-titration sleep studies. Eleven patients had mild sleep apnea, 11 patients had moderate sleep apnea, and six patients had severe sleep apnea. A minimum adherence time of four hours per night and use of at least five out of seven nights a week was considered to be compliant with treatment to align with current Medicare requirements for compliance with CPAP. Efficacy was measured by comparing the average AHI on posttreatment HST to the average pretreatment baseline AHI. Additionally, treatment effectiveness was measured by evaluating pretreatment and posttreatment QOL indices; including the Pittsburgh Sleep Quality Index (PSQI), the Functional Outcomes of Sleep (FOSQ), and the Insomnia Severity Index (ISI). Snoring was evaluated using the Snore Severity Score (SSS). Actual sleep time was estimated using patient reports.

Of the 28 subjects who completed the study, the pretreatment mean AHI was 21.8 ± 12.1 per hour (ranging from 6 to 49) with a posttreatment mean AHI of 8.2 ± 5.9, ranging from 1.2 to 14.5. MDA was calculated as the product of the AHI percent reduction after treatment and the overall compliance rate (as a percentage of oral appliance use on average per night). QOL questionnaires showed significant improvement after treatment. MAD was found to be an effective first-line treatment for patients with mild, moderate, and severe sleep apnea with excellent compliance rates, similar to or better than CPAP, and an equal or better MDA of

56.7% compared to literature values of 50% for CPAP. The authors concluded that MAD should be considered an effective first-line treatment for patients with mild and moderate sleep apnea and for severe sleep apnea for patients who prefer, refuse, or are not candidates for CPAP. Long-term adherence was not evaluated in this study.

Section Summary: Oral Appliance Therapy Device with Compliance Recorder
Two studies were identified; the studies included patients with diagnosed obstructive sleep apnea. One study was a feasibility study with 8 patients in which recorded compliance and mean nightly usage data was obtained. The other study evaluated the effectiveness of a mandibular advancement device fitted with a compliance tracker as a first-line treatment in a population of 28 subjects with mild to severe obstructive sleep apnea. Mean disease alleviation (MDA) was calculated to compare the treatment effectiveness of MAD to historical continuous positive airway pressure (CPAP) effectiveness data. MAD was found to be an effective first-line treatment for patients with mild, moderate, and severe sleep apnea with excellent compliance rates, similar to, or better than CPAP, and an equal or better MDA of 56.7% compared to literature values of 50% for CPAP. Long-term adherence was not evaluated in this study. Limitations included small numbers of participants and lack of long-term data.

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) and 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 positive airway pressure (CPAP) during sleep. A diagnostic sleep study may be followed by a trial of auto-adjusting positive airway pressure (APAP) to evaluate the 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 receive novel OSA treatments (e.g., palate expansion, nasal expiratory positive airway pressure (EPAP), oral pressure therapy, tongue stimulation, supine vibration, oral appliance therapy device with compliance recorder), 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 AHI, with a minor impact on oxygenation, and a decrease in Epworth Sleepiness Scale (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. Single-arm studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is uncertain. 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 on oral appliance therapy device with compliance recorder in individuals with OSA has been reported in two studies, one a feasibility study with 8 patients in which recorded compliance and mean nightly usage data was obtained. The second study evaluated the effectiveness of a mandibular advancement device fitted with a compliance tracker as a first-line treatment in a population of 28 subjects. Although there was evidence to support efficacy, the studies were limited by small numbers of participants and lack of long-term data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

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. (42) 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. (43, 44) 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. (45) The levels of recommendation are "standard" (generally accepted patient-care strategy, with a high degree of certainty; level 1 to 2 evidence), "guideline" (moderate degree of clinical certainty; level 2 to 3 evidence), or "option" (uncertain clinical use; insufficient or inconclusive evidence).

Treatment with positive airway pressure (PAP)

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

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

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

The AASM (2019) also published a clinical practice guideline on the treatment of OSA with PAP that was based on a systematic review of the evidence. (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 OA therapy. (20) The 2 societies provided a recommendation of "standard" that sleep physicians consider prescription of OA, rather than no treatment, for adults with OSA who are intolerant of CPAP therapy or prefer alternative therapy. The quality of evidence was rated as moderate. "Guideline" recommendations were provided for the use of custom, titratable appliance over noncustom oral devices, that qualified dentists provide oversight, that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, and that patients return for periodic office visits with a qualified dentist and a sleep physician.

American Heart Association

In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease. (46) 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 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). (47) The guidelines noted that

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

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

American Thoracic Society

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

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

National Institute for Health and Care Excellence

NICE provides guidance on medical management in individuals with varying degrees of OSA. (49) 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 maybe 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.

Ongoing and Unpublished Clinical Trials

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

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	94660
HCPCS Codes	A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046, A7049, E0470, E0471, E0485, E0486, E0490, E0491, E0492, E0493, E0530, E0561, E0562, E0601, K1027, K1037, [Deleted 1/2024: K1001, K1028, K1029]

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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 02 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 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 apnea: estimation from three randomized 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):148-173. 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):143-147. 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):240-243. PMID 16494092
10. Morgenthaler TI, Aurora RN, Brown T, 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 update for 2007. An American Academy of Sleep Medicine report. Sleep. Jan 2008; 31(1):141-147. 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):330-333. 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):247-251. 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):273-278. 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):919-931. 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):477-481. 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):707-718. 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. 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

22. 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
23. 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
24. Singh GD, Griffin T, Cress SE. Biomimetic oral appliance therapy in adults with severe obstructive sleep apnea. J Sleep Disord Ther. 2016; 5:227.
25. 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.
26. Krakow B, Ulibarri V, Melendrez D, et al. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia patients with sleep disordered breathing to positive airway pressure (PAP-NAP). J Clin Sleep Med. Jun 15 2008; 4(3):212-222. PMID 18595433
27. Ulibarri VA, Krakow B, McIver ND. The PAP-NAP one decade later: patient risk factors, indications, and clinically relevant emotional and motivational influences on PAP use. Sleep Breath. Dec 2020; 24(4):1427-1440. PMID 31898192
28. 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
29. 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 01 2011; 34(4):479-485. PMID 21461326
30. 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
31. 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. Jun 15 2014; 10(6):663-669. PMID 24932147
32. 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
33. 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
34. Baptista PM, Martinez 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):1883. PMID 33925376
35. 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

36. 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):139-147. PMID 25515276
37. 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
38. 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
39. 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):1209-1215. PMID 25061249
40. Beyers J, Dieltjens M, Kastoer C, et al. Evaluation of a trial period with a sleep position trainer in patients with positional sleep apnea. J Clin Sleep Med. Apr 15 2018; 14(4):575-583. PMID 29609712
41. Buyse B, Ciordas S, Hoet F, et al. Positional obstructive sleep apnoea: challenging findings in consecutive patients treated with a vibrating position trainer. Acta Clin Belg. Dec 2019; 74(6):405-413. PMID 30433857
42. American Academy of Otolaryngology-Head and Neck Surgery. Position Statement: Treatment of obstructive sleep apnea. (2021) Available at <https://www.entnet.org> (accessed May 9, 2023).
43. Section on Pediatric Pulmonology, Subcommittee on Obstructive Sleep Apnea Syndrome. American Academy of Pediatrics. Clinical Practice Guideline: Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome. Pediatrics. Apr 2002; 109(4):704-712. PMID 11927718
44. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. Sep 2012; 130(3):576-584. PMID 22926173
45. 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):263-276. PMID 19960649
46. 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):e56-67. PMID 34148375
47. ASMBS Clinical Issues Committee. Peri-operative management of obstructive sleep apnea. Surg Obes Relat Dis. May-Jun 2012; 8(3):e27-32. PMID 22503595
48. 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 01 2016; 193(9):e37-54. PMID 27128710
49. National Institute for Health and Care Excellence (NICE). Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s: NG202. Published Aug 20, 2021. Available at <https://www.nice.org.uk> (accessed May 9, 2023).
50. 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). Available at <https://www.cms.gov> (accessed May 10, 2023).

51. Centers for Medicare & Medicaid Services (CMS). CMS Manual System: Pub 100-03 Medicare National Coverage Determinations. Transmittal 96. Change request 6048 (2008). Available at <https://www.cms.gov> (accessed May 9, 2023).
52. Rana AM, Sankari A. Central Sleep Apnea. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan. PMID 35201727
53. U.S. Food and Drug Administration. ProSomnus EVO Sleep and Snore Device, ProSomnus EVO Sleep and Snore Device with Patient Monitoring. (2020) (K202529). Available at <https://www.accessdata.fda.gov> (accessed March 19, 2024).
54. Hu J, Liptak L. Evaluation of a New Oral Appliance with Objective Compliance Recording Capability: A Feasibility Study. Journal of Dental Sleep Medicine. 2018; 5(2):47-50. Available at <https://www.aadsm.org> (accessed March 20, 2024).
55. Stern J, Lee K, Kuhns D, et al. Efficacy and Effectiveness of the ProSomnus® [IA] Sleep Device for the Treatment of Obstructive Sleep Apnea: EFFECTS Study. Cureus. Jun 2 2021; 13(6):e15391. PMID 34249542

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
09/15/2024	Document updated with literature review. The following changes were made to Coverage: 1) Clarified symptoms associated with an AHI of 5 or higher in adults; 2) Added criteria for treatment with APAP in adults; 3) Modified conditional criteria for Bilevel Positive Airway Pressure (with or without back-up rate feature) for established Central Sleep Apnea (CSA); and 4) Added "The use of an oral appliance therapy device with a compliance recorder (OAT-CR) (e.g., and ProSomnus EVO® Sleep and Snore Device with Patient Monitoring) is considered experimental, investigational and/or unproven for the treatment of OSA." The following references were added: 22, 23, 49, and 52-55, others updated.
02/01/2023	New medical document originating from MED204.005 Diagnosis and Medical Management of Sleep Related Breathing Disorders. Coverage position on medical management of sleep related breathing disorders remains unchanged with the following exceptions: the following was added to the

	Coverage: 1) The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered experimental, investigational and/or unproven; 2) The use of a sleep positioning trainer with vibration is considered experimental, investigational and/or unproven for the treatment of positional OSA; and 3) The use of daytime electrical stimulation of the tongue is considered experimental, investigational and/or unproven for the treatment of OSA.