Medical Policy

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Title: Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

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Populations	Interventions	Comparators	Outcomes
Individuals: • With suspected obstructive sleep apnea	Interventions of interest are: • Home sleep apnea testing with at least 3 recording channels	Comparators of interest are: • Polysomnography	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Resource utilization
Individuals: • With suspected obstructive sleep apnea	Interventions of interest are: • Limited channel home sleep apnea testing	Comparators of interest are: • In-laboratory polysomnography • Home sleep testing with at least 3 recording channels	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Resource utilization
Individuals: • With obstructive sleep apnea	Interventions of interest are:	Comparators of interest are: • Weight loss	Relevant outcomes include: • Symptoms

Populations	Interventions	Comparators	Outcomes
	• Positive airway pressure devices	• Position therapy	• Functional outcomes • Quality of life
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Oral appliances	Comparators of interest are: • Continuous positive airway pressure therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Neuromuscular electrical tongue stimulation	Comparators of interest are: • Continuous positive airway pressure therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Novel obstructive sleep apnea treatment (eg, palate expansion, expiratory positive airway pressure, oral pressure therapy)	Comparators of interest are: • Continuous positive airway pressure therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

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. Polysomnography and portable sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone [PAT], actigraphy, and oxygen saturation) are established methods for diagnosing OSA. Other proposed methods of diagnosing OSA include limited channel home sleep monitors. 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.

OBJECTIVE

The objective of this evidence review is to evaluate the evidence for established and novel methods of diagnosing and treating obstructive sleep apnea.

BACKGROUND

Obstructive Sleep Apnea

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

more common in ethnic minority groups, there are data supporting an increased risk of OSA in African Americans and American Indians.

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

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

Cardiovascular and pulmonary systems can also be affected by OSA.[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.

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 associated arousal.
RERA	Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea.
Respiratory event reporting	
AHI	The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep.
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available.
OSA	Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep
Mild OSA	In adults: AHI or RDI of 5 to <15. In children: AHI ≥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	PAP may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure.
PAP failure	Usually defined as an AHI >20 events per hour while using CPAP.

Terms	Definition
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; EEG: electroencephalogram; OSA: obstructive sleep apnea; PAP: positive airway pressure; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal: UARS: upper airway resistance syndrome.

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

Treatment

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

REGULATORY STATUS

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

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

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

Table 2. Novel Devices for OSA Diagnosis and Treatment

Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
Diagnosis					
Accusom	Novasom, Inc	The ACCUSOM device is a battery and line-powered ventilatory effort recorder. The	K110486	MNR	2011

Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
		ACCUSOM device is indicated for use in the diagnostic evaluation of adults with possible sleep apnea.			
SOMNOtouch RESP	Somnomedics, GMBH	The SOMNOtouch RESP is a portable physiological signal recorder. It is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of sleep disorders and sleep related respiratory disorders of adult patients.	K140861	MNR	2015
SleepImage System	MyCardio	Software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor to aid in the evaluation of sleep disorders.	K163696	MNR	2017
ZMachine synergy	Consolidated Research of Richmond, Inc	The Zmachine Synergy is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep disorders.	K172986	OLV, OMC, MNR	2017
SleepImage System	MyCardio	The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality. The SleepImage System analyzes, displays and summarizes Electrocardiogram (ECG) or Plethysmogram (PLETH) data, typically collected during sleep, that is intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for children, adolescents and adults. The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing. The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.	K182618	MNR	2019

Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
ApneaTrak	Cadwell Industries, Inc	The Cadwell ApneaTrak device is intended for home sleep testing, including the acquisition of physiological and environmental data. The recorded signals are then transmitted to a PC so that they can be viewed. ApneaTrak is intended for use on patients older than 2 years of age.	K192624	MNR	2020
Belun ring	Belun Technology Company Limited	The Belun Sleep System BLS-100 is a wearable device intended to record, analyze, display, export, and store biophysical parameters to aid in evaluating moderate to severe sleep-related breathing disorders of adult patients suspected of sleep apnea.	K211407	MNR	2021
ANNE Sleep	Sibel, Inc.	ANNE Sleep is a wearable sensor system intended for use in the collection, analysis, display, and storage of physiological parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea.	K220095	MNR	2022
BresoDX1	Bresotec Inc	BresoDX1 is indicated for use as an aid in the diagnosis of moderate to severe sleep apnea in adult patients. BresoDX1 records a patient's physiological signals during sleep and scores apneas and hypopneas.	K220012	MNR	2022
Cerebra Sleep System	Cerebra Medical, Ltd	The Cerebra Sleep System is an integrated diagnostic platform that acquires, transmits, analyzes, and displays physiological signals from adult patients, and then provides for scoring (automatic and manual), editing, and generating reports. The system uses polysomnography (PSG) to record the electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), electromyogram (EMG), accelerometry, acoustic signals, nasal airflow, thoracic and abdomen respiratory effort, pulse rate, and oxyhemoglobin saturation, depending on the sleep study configuration.	K213007	OLV	2022
NightOwl	Ectosense Nv	The NightOwl is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea.	K220028	MNR	2022

Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
Sunrise	Sunrise SA	The Sunrise device is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years and older with suspicions of sleep breathing disorders.	K222262	MNR	2022
WatchPAT	Itamar Medical, Ltd	The WatchPAT ONE (WP1) device is a noninvasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position.	K223675	MNR	2022
AcuPebble OX100	Acurable Limited	AcuPebble Ox100 is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of adult patients with, or with suspected, obstructive sleep apnea (OSA)	K222950	MNR	2023
Onera STS	Onera B.V	Onera STS measures and records multiple physiological parameters from a patient during a sleep study which are used by clinicians to make a decision on the diagnosis of sleep disorders.	K223573	MNR	2023
Wesper Lab	Wesper, Inc	The Wesper Lab is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. Wesper Lab records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep apnea by trained personnel.	K221816	MNR	2023
Treatment					
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 apnea from sleeping in the supine position.	K180608	MYB	2018

Device	Manufacturer	Description	510(K) Number	FDA Product Code	Year
eXciteOSA®	Signifier Medical Technologies	The device delivers neuromuscular stimulation during the day to strengthen the tongue in order to reduce snoring and mild sleep apnea. It is used for 20 minutes once a day for a period of 6 weeks, and once a week thereafter.	K223446	QNO	2021
Respire Clear	Respire Medical, LLC	The device is an oral appliance used in the treatment of mild to moderate OSA. It helps move a patient's jaw forward, thus opening their airways, and allowing them to breathe more easily throughout the night.	K214096	LRK; LQZ	2022
CARE (Complete Airway Repositioning and/or Expansion)	Vivos Therapeutics, Inc	The device is intended to reduce nighttime snoring and to treat mild and moderate obstructive sleep apnea in adults, 18 years of age and older. The device is also intended to treat moderate and severe obstructive sleep apnea in adults, 18 years of age and older along with positive airway pressure devices and/or myofunctional therapy, as needed.	K230947	LRK; LQZ	2023

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

POLICY

A. **Diagnosis**

1. Unattended (unsupervised) Home Sleep Apnea Test

   a. A single unattended (unsupervised) home sleep apnea test with a minimum of 3 recording channels with the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or alternatively peripheral arterial tone (PAT), oximetry and actigraphy may be considered **medically necessary** in adults who are at high-risk for obstructive sleep apnea (OSA) and have no evidence of a health condition that might alter ventilation or require alternative treatment, i.e.:
      I. central sleep apnea
      II. heart failure
      III. chronic pulmonary disease
      IV. obesity hypoventilation syndrome
      V. neuromuscular disorders with sleep-related symptoms
      VI. injurious or potentially injurious parasomnias
      VII. narcolepsy

      Policy Guidelines defines high risk.

   b. A single unattended (unsupervised) home sleep apnea test with a minimum of recording channels as described in A 1 a may be considered **medically necessary** as a screening tool in individuals who are scheduled for bariatric surgery and have no evidence of a health condition that might alter ventilation or require alternative treatment (see Policy Guidelines).

   c. Unattended home sleep apnea tests are considered **experimental / investigational** in children (<18 years of age).

   d. Repeat unattended (unsupervised) home sleep apnea test with a minimum of 3 recording channels with the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or alternatively PAT, oximetry and actigraphy, may be considered **medically necessary** in adults under the following circumstances:
      I. To assess efficacy of surgery or oral appliances or devices; **OR**
      II. To reevaluate the diagnosis of OSA and need for continuous positive airway pressure (CPAP), eg, if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued.

2. Supervised Polysomnography (PSG)

   a. Supervised polysomnography (PSG) performed in a sleep laboratory may be considered **medically necessary** in individuals with a moderate or high risk of OSA in the following situations:
      I. Pediatric individuals (i.e., < 18 years of age) **OR**
      II. When individuals do not meet criteria for an unattended home sleep apnea test as described above **OR**
      III. A previous home study failed to establish the diagnosis of OSA in a individual with a high risk of OSA **OR**
      IV. A previous home study was technically inadequate **OR**
      V. Failure of resolution of symptoms or recurrence of symptoms during treatment **OR**
      VI. When testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy **OR**
      VII. Presence of a comorbidity that might alter ventilation or decrease the accuracy of a home sleep apnea test, including, but not limited to: heart failure, neuromuscular disease, chronic pulmonary disease, obesity hypoventilation syndrome

   b. A repeated supervised polysomnography (PSG) performed in a sleep laboratory may be considered **medically necessary** in individuals who meet criteria in A 2 a for an in-laboratory PSG under the following circumstances:
      I. To initiate and titrate continuous positive airway pressure (CPAP) in adults who have:
         i. An Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of at least 15 events per hour, **OR**
         ii. An AHI or RDI of at least 5 events per hour in an individual with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke)

      Note: A split-night study, in which moderate to severe OSA is documented during the first portion of the study using polysomnography, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines).

      II. To initiate and titrate CPAP in children:
         i. In pediatric individuals, an AHI or RDI of ≥ 5 **OR**
         ii. An AHI or RDI ≥1.5 in a individual with excessive daytime sleepiness, behavioral problems or hyperactivity
      III. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices

3. Supervised or unattended home sleep apnea tests that do not meet the above criteria are considered **experimental / investigational**.

4. Multiple sleep latency testing is considered **experimental / investigational** in the diagnosis of OSA.

B. **Medical Management**

1. Auto-adjusting positive airway pressure (APAP) may be considered **medically necessary** for the titration of pressure in adults with clinically significant OSA defined as those who have:
   a. An Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), or Respiratory Event Index (REI) of at least 15 events per hour, **OR**

   b. An AHI, RDI, or REI of at least 5 events per hour in a individual with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke); OR

   c. If there is a significant change in weight or change in symptoms suggesting that continuous positive airway pressure (CPAP) should be reiterated or possibly discontinued.

2. CPAP may be considered **medically necessary** in adult or pediatric individuals with clinically significant OSA
   a. Clinically significant OSA in adults is:
      I. An AHI, RDI, or REI ≥15, **OR**
      II. An AHI, RDI, or REI ≥5 in a individual with one or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

   b. Clinically significant OSA in pediatric individuals is,
      I. An AHI or RDI ≥5 **OR**
      II. An AHI or RDI ≥1.5 in a individual with excessive daytime sleepiness, behavioral problems or hyperactivity

3. Bilevel positive airway pressure (PAP) or APAP 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 (BiPAP) is found to be more effective in the sleep lab.

4. Intraoral appliances (tongue-retaining devices or mandibular advancing / positioning devices) may be considered **medically necessary** in adults with clinically significant OSA under the following conditions:
   a. OSA, defined by an AHI or REI of at least 15 events per hour or an AHI, RDI, or REI of at least 5 events per hour in a individual with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke)
      AND
   b. A trial with CPAP has failed or is contraindicated
      AND
   c. The device is prescribed by a treating physician
      AND
   d. The device is custom-fitted by a dentist or by qualified dental personnel under the supervision of a dentist
      AND
   e. The individual has been evaluated and cleared by a dentist for the device.

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

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

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

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

8. The use of neuromuscular electrical tongue stimulation is considered **experimenta**l / **investigational** for the treatment of OSA.

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

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

POLICY GUIDELINES

A. **Specialist Training**

Polysomnographiy or home sleep apnea testing should be performed in appropriately selected individuals and the test summary results reviewed by a physician who is trained in sleep medicine.

Medical professionals who interpret a polysomnogram or home sleep study should be trained in sleep medicine and should review the raw data from PSG and home sleep studies to detect artifacts and data loss.

Treatment of individuals diagnosed with 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 (eg, review of symptoms and device utilization at 90 days with a minimum of 4 hours per night for at least 5 nights per week).

B. **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 obstructive sleep apnea (OSA):

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

C. **OSA In Children**

The presentation of obstructive sleep apnea (OSA) in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a BMI greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) greater than 1.5 events per hour is considered abnormal (an AHI or RDI ≥ 10 events per hour may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. Continuous positive airway pressure (CPAP) is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

D. **Bariatric Surgery Individuals**
Screening for OSA should be performed routinely in individuals scheduled for bariatric surgery, due to the high prevalence of OSA in this population. The optimal screening approach is not certain. An in-laboratory PSG or home sleep study is the most accurate screening method. Some experts recommend a symptom-based screening instrument, followed by PSG in individuals who exceed a certain threshold, as an alternative to performing PSG in all individuals. It should be noted that there is a high prevalence of obesity hypoventilation syndrome in individuals who are candidates for bariatric surgery. Therefore, obesity hypoventilation syndrome should be ruled out prior to home sleep testing in this population.

E. **Significant Weight Change**
There is no established threshold for significant change in weight. Studies have reported improvements in OSA with an average weight loss of 20 kg or 20% of body weight.

F. **Multiple Sleep Latency Test**
The multiple sleep latency test (MSLT) is an objective measure of the tendency to fall asleep in the absence of alerting factors, while the maintenance of wakefulness test (MWT) is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). The MSLT and MWT are not routinely indicated in the evaluation and diagnosis of OSA or in the assessment of change following treatment with CPAP. The MSLT may be indicated in the evaluation of individuals with suspected narcolepsy to confirm the diagnosis (often characterized by cataplexy, sleep paralysis, and hypnagogic/hypnopompic hallucinations) or to differentiate between suspected idiopathic hypersomnia and narcolepsy. Narcolepsy and OSA can co-occur. Because it is not possible to differentiate between the excessive sleepiness caused by OSA and by narcolepsy, OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.

G. **Split-Night Studies**
American Academy for Sleep Medicine (AASM) practice parameters (2005) have indicated that a split-night study (initial diagnostic polysomnography [PSG] followed by CPAP titration during PSG on the same night) is an alternative to 1 full night of diagnostic PSG followed by a second night of titration if the following 4 criteria are met:

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

H. **Categorization of Polysomnography and Portable Monitoring**

1. Full correspondence does not exist between Current Procedural Terminology (CPT) codes and the most current categorization scheme for the different types of studies. The 2005 practice parameters from the American Academy of Sleep Medicine list 4 types of monitoring procedures:
   a. type 1, standard attended in-lab comprehensive PSG;
   b. type 2, comprehensive portable PSG;
   c. type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of 4 or more channels of monitoring; and
   d. type 4, continuous single or dual bioparameters, consisting of 1 or 2 channels, typically oxygen saturation, or airflow.

   Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and PSG are often used interchangeably. CPT coding distinguishes between sleep studies that do not include electroencephalographic (EEG) monitoring, and PSG, which includes EEG monitoring. PSG is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the individual's home. There are no specific codes for remotely monitored home sleep studies. They would likely be reported with the CPT code for the sleep study with the GT modifier ("via interactive audio and video telecommunications systems") appended. There is no CPT code for "unattended" PSG.
2. Cardiorespiratory sleep studies without EEG may be called polygraphic studies and can be attended or unattended by a technologist. CPT codes 95807 and 95806 distinguish polygraphic sleep studies that are attended or unattended, but there are no codes that distinguish between type 3 and type 4 sleep studies. A wide variety of portable monitors and proprietary automated scoring systems are being tested and marketed, but the optimum combination of sensors and scoring algorithms is currently unknown. Current recommendations are that the portable monitoring device have 4 channels (oxygen saturation, respiratory effort, respiratory airflow, heart rate) and permit review of the raw data. Type 4 monitors with fewer than 3 channels are not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional trained in sleep medicine to detect artifacts and data loss.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 9, 2023.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of

life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

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

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

MULTICHANNEL HOME SLEEP APNEA TESTING

Clinical Context and Test Purpose

The purpose of home sleep apnea tests in individuals with suspected obstructive sleep apnea (OSA) is to diagnose the condition and to inform a decision on appropriate treatment.
The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with suspected OSA.

Interventions

The test being considered is home sleep apnea testing. Tests reviewed are multichannel home sleep testing.

Comparators

The established test for OSA is in-laboratory polysomnography (PSG). Laboratory PSG is a more complex procedure than home testing and is more limited in its availability.

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) (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 (eg, watching TV, sitting quietly in a car, or sitting and talking to someone)	An ESS of ≥10 is considered excessively sleepy
FOSQ	30 questions	Disease-specific quality of life questionnaire that evaluates functional status related to excessive sleepiness	A score of ≥18 is the threshold for normal sleep-related functioning, and a change of ≥2 points is considered a clinically meaningful improvement

AHI: Apnea/Hypopnea Index; ESS: Epworth Sleepiness Scale; FOSQ: Functional Outcomes of Sleep Questionnaire; MID: minimal important difference; ODI: oxygen desaturation Index; OSA: obstructive sleep apnea; QOL: quality of life.

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

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

Study Selection Criteria

For the evaluation of clinical validity of home sleep apnea testing, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

REVIEW OF EVIDENCE

Systematic Reviews

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.[4,] Reviewers found strong evidence that an AHI greater than 30 events per hour is an independent predictor of all-cause mortality, with low or insufficient evidence for an association between AHI and other clinical outcomes. Reviewers found moderate evidence that type 3 and 4 monitors may have the ability to accurately predict an AHI suggestive of OSA and that type 3 monitors perform better than type 4 monitors at AHI cutoffs of 5, 10, and 15 events per hour.

Randomized Controlled Trials

Home sleep testing with 3 recording channels that include respiratory effort, airflow, and oxygen saturation, but not heart rate, are considered by some, including the Centers for Medicare & Medicaid, to be sufficient for home sleep apnea tests. Corral et al (2017) reported a multicenter noninferiority trial of home sleep testing using a 3-channel monitor compared with in-laboratory PSG in 430 patients.[5,] Included in the study were patients referred to tertiary hospitals in Spain for suspected OSA, who had snoring or sleep apneas observed by a partner, ESS score of 10 or greater, and absence of clinical suspicion of any other sleep pathology. Both groups of patients who were diagnosed with OSA received continuous positive airway pressure (CPAP) titration with a single auto-adjusting positive airway pressure (APAP) session at home. The median baseline ESS score was 13 in both groups. CPAP was indicated in 68% of patients in the PSG arm compared with 53% in the home sleep testing group, with the difference attributed to the underestimation of AHI in-home sleep studies. All patients, including those treated with CPAP and those who were not, were assessed at a 6-month follow-up. ESS score improved by -4.2 (95% confidence interval [CI], -4.8 to -3.6) in the home sleep testing group and by -4.9 (95% CI, -5.4 to -4.3) in the PSG group. With a noninferiority margin of 2 points on the ESS, home sleep testing was noninferior to in-laboratory PSG.

Section Summary: Multichannel Home Sleep Apnea Testing

Based on this evidence and society guidelines, portable monitoring with a minimum of 4 recording channels (including oxygen saturation, respiratory movements, airflow, an electrocardiogram or heart rate), or with a device that measures peripheral arterial tone (PAT), actigraphy, and oxygen saturation, for the diagnosis of OSA in adults who are at high-risk for OSA improves outcomes, when clinical evaluation and follow-up are conducted by a medical professional experienced in the diagnosis and treatment of sleep disorders.

LIMITED CHANNEL HOME SLEEP APNEA TESTING

Clinical Context and Test Purpose

The purpose of limited channel home sleep apnea tests in individuals with suspected OSA is to diagnose the condition and to inform a decision on appropriate treatment.

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

Populations

The relevant population of interest is individuals with suspected OSA.

Interventions
The test being considered is home sleep apnea testing. Tests reviewed are limited channel sleep testing (e.g., APAP, Apnea Risk Evaluation System).

Comparators
The established test for OSA is in-laboratory PSG. Laboratory PSG is a more complex procedure than home testing and is more limited in its availability. Other comparators include home sleep testing with at least 3 recording channels.

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, as described in Table 3, above.

Beneficial outcomes of a true-positive test 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
For the evaluation of clinical validity of home sleep apnea testing, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores).
- Included a suitable reference standard.
- Patient/sample clinical characteristics were described.
- Patient/sample selection criteria were described.

REVIEW OF EVIDENCE

USE OF AUTO-ADJUSTING POSITIVE AIRWAY PRESSURE FOR DIAGNOSIS AND TREATMENT SUPERVISED BY A SLEEP SPECIALIST

Randomized Controlled Trials
Mulgrew et al (2007) published a randomized validation study of the diagnosis and management of OSA with a single-channel monitor followed by APAP.[6,] They developed a diagnostic algorithm that had a 94% positive predictive value for moderate-to-severe OSA assessed by PSG. Patients who passed the screening (N=68) were randomized to attend in-laboratory PSG with CPAP titration or home monitoring with a portable APAP unit. No difference was observed between lab PSG and home-managed patients for any of the outcome measures. Senn et al (2006) assessed whether an empirical approach, using a 2-week trial of APAP, could effectively diagnose OSA.[7,] Patients (N=76) were included in the study if they had been referred by primary care physicians for evaluation of suspected OSA, were habitual snorers, complained of daytime sleepiness, and had an ESS score of 8 or greater (mean, 13.6). At the end of the 2-week trial, patients were asked to rate the perceived effect of treatment and to indicate whether they had used CPAP for more than 2 hours per night and were willing to continue treatment. Patients without a clear benefit of CPAP received a further evaluation, including clinical assessment and

PSG. Compared with PSG, patient responses showed a sensitivity of 80%, a specificity of 97%, a positive predictive value of 97%, and a negative predictive value of 78%.

Berry et al (2008) randomized 106 patients referred for a sleep study for suspected OSA at a local Veterans Administration center to portable monitoring followed by APAP or to PSG for diagnosis and treatment.[8,] Patients were screened with a detailed sleep and medical history questionnaire, and patients on α-blockers or not in sinus rhythm were excluded due to the type of portable monitoring device used (Watch-PAT 100). Of the 53 patients randomized to PSG, 6 (11%) did not have PSG-defined OSA; in the portable monitoring arm, 4 (8%) of 53 patients were found not to have OSA. Treatment outcomes were similar in both groups, with a 7-point improvement in ESS score, 3-point improvement in the FOSQ score, and a machine estimate of residual AHI of 3.5 events per hour in the portable monitoring APAP group and 5.3 in the PSG group.

The racial/ethnic diversity of enrolled patients was not reported in any of the above RCTs. More than 75% of enrolled patients in all 3 trials were men.

APNEA RISK EVALUATION SYSTEM

Nonrandomized Comparative Studies

Ayappa et al (2008) reported on a validation study of a small apnea monitor that is self-applied to the forehead.[9,] The device measures blood oxygen saturation and pulse rate, airflow, snoring levels, head movement, and head position. The study enrolled 80 individuals with a high likelihood of OSA and 22 with a low risk of OSA; results of simultaneous Apnea Risk Evaluation System recording and PSG were available for 92 individuals. When healthy subjects were excluded from the analysis, sensitivity (91%) and specificity (92%) were relatively high for an AHI of 15 or more events per hour but dropped considerably with an AHI between 5 and 15 (sensitivity, 97%; specificity, 78%). Five percent of the subjects could not tolerate the device and were excluded from the analysis.

SLEEPIMAGE SYSTEM

Randomized Controlled Trials

The SleepImage System is cloud-based software as a medical device that generates AHI from data recorded with a single photoplethysmogram sensor. The SleepImage algorithms calculate heart rate variability, respiration, and oxygen saturation with cardiopulmonary coupling analysis. Hilmisson et al (2020) compared results calculated by the SleepImage System with manually scored PSG in 805 children 5 to 9.9 yrs of age who participated in the Childhood Adenotonsillectomy Trial (CHAT).[10,] The CHAT study included 1244 habitually snoring children who were referred for PSG. A total of 805 children had successfully collected data from the sensor, while 439 did not. Of the 805 children with data, 47% were male, 61% were African American, and 29% were White. Concordance between the SleepImage-derived AHI and PSG-derived AHI in the successful recordings is shown in Table 4. Kappa was 0.81, 0.89, and 0.91 for mild, moderate, and severe sleep apnea, respectively. A proposed benefit is that this would be easier for children compared to a test requiring multiple sensors in a sleep laboratory and improve access. Further study in a wider population is needed to evaluate whether this system might be a suitable method for evaluating sleep parameters in the home.

Table 4. Clinical Validity of the SleepImage System

Study	Initial N	Final N	Excluded Samples	Prevalence of Condition	Clinical Validity: Agreement (95% CI)		
					Mild Sleep Apnea AHI > 1.0	Moderate Sleep Apnea AHI > 5.0	High Risk AHI > 10.0
Hilmission et al (2020)[10,]	1244	805	439	64%	0.914 (0.895 to 0.934)	0.967 (0.954 to 0.979)	0.986 (0.978 to 0.994)

AHI: Apnea/Hypopnea Index; CI: confidence interval.

Section Summary: Limited Channel Home Sleep Apnea Testing
The evidence for limited channel home sleep apnea testing (includes type 4 monitors) in patients who have OSA consists of studies on diagnostic accuracy. A number of questions remain about the ability of these home sleep apnea tests to detect clinically significant OSA without sensors for respiratory effort, airflow, and oxygen saturation (or alternatively PAT, actigraphy, and oxygen saturation).

POSITIVE AIRWAY PRESSURE DEVICES

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

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

Populations
The relevant population of is patients 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 individual compliance due to the need to wear a face or nasal mask.

Outcomes

The general outcomes of interest are the number of apneas or hypopneas during sleep, measured by the Apnea/Hypopnea Index (AHI), and subjective symptoms of sleepiness, typically measured with the Epworth Sleepiness Scale (ESS) or the Functional Outcomes of Sleep Questionnaire (FOSQ). Additional health outcome measures relevant to OSA are summarized in Table 5.

Table 5. 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., watching TV, sitting quietly in a car, or sitting and talking to someone)	An ESS of ≥10 is considered excessively sleepy. A decrease of 2 points is considered the MID.[3,]
FOSQ	30 questions	Disease-specific QOL questionnaire that evaluates functional status related to excessive sleepiness	A score of ≥18 is the threshold for normal sleep-related functioning, and a change of ≥2 points is considered a clinically meaningful improvement

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

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

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

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

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

REVIEW OF EVIDENCE

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 to 57 months). The analysis found no significant association of PAP with a composite outcome of acute coronary syndrome events, stroke, or vascular death (relative risk, 0.77; 95% CI, 0.53 to 1.13). Trials were grouped according to adherence to PAP (<4 vs ≥4 hours/day), type of sleep apnea (obstructive vs. central), and type of PAP (CPAP vs. adaptive servo-ventilation). Meta-regression identified no association between PAP with outcomes for different levels of apnea severity, follow-up duration, or adherence to PAP. As reported by McEvoy et al (2016), the largest trial included in the meta-analysis was the Sleep Apnea Cardiovascular Endpoints RCT, which found no benefit of CPAP on the primary composite outcome of death or hospitalization for cardiovascular events in 2717 adults with moderate-to-severe OSA and cardiovascular disease who were followed for a median of 44 months.[15,] With a mean duration of adherence to CPAP therapy of 3.3 hours per night, CPAP significantly reduced daytime sleepiness (adjusted difference in ESS score, -2.5; 95% CI, -2.8 to -2.2; p<.001) and improved health-related QOL and mood. Lisan et al (2019) reported 11-year follow-up of a cohort of 392 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 H_2O. 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 review.

Populations
The relevant population of is individuals with OSA.

Interventions
The therapy being considered is oral appliances during sleep.

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

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

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

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

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

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

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

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

REVIEW OF EVIDENCE

Systematic Reviews

In the AHRQ report (2011) on the diagnosis and treatment of OSA in adults, the strength of the evidence that MADs improve sleep apnea signs and symptoms was rated moderate.[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. Additional meta-analyses have supported these findings by reporting pooled improvements from baseline following MADs in AHI, ESS, and ODI for durations over 1 year and within mild, moderate, and severe OSA during stratified analysis.[21,22,]

READY-MADE VERSUS CUSTOM-MADE MANDIBULAR ADVANCEMENT DEVICES

Randomized Controlled Trials

Johal et al (2017) reported on a randomized crossover trial of ready-made 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.

NEUROMUSCULAR ELECTRIC TONGUE STIMULATION

Clinical Context and Therapy Purpose
The purpose of neuromuscular electric tongue stimulation in individuals who have OSA is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations
The relevant population of is individuals with OSA.

Interventions
The therapy being considered is neuromuscular electric tongue stimulation with the ExciteOSA device (Signifier Medical Technologies).

Neuromuscular electrical tongue stimulation utilizes a device to deliver electrical impulses to nerves, resulting in muscle contractions. By electrically stimulating the muscles, neuromuscular electric stimulation may improve range of motion and counteract the negative consequences of muscle disuse or paralysis. Research suggests that enhancing the activity of the genioglossus muscle and other upper airway muscles can have a beneficial impact on OSA symptoms. The eXciteOSA device focuses on stimulating the upper airway dilator muscles that support the airway while the patient is awake in daily 20-minute sessions. A companion smartphone application

allows for setting parameters of the device, such as intensity and duration, and can be used by healthcare providers to monitor adherence to therapy.

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

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

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

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

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

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

REVIEW OF EVIDENCE

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

Prospective Cohort Studies

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

Three studies reported on an overlapping population from the same single-arm clinical trial (NCT03829956).[28,29,30,] Trial participants used the eXciteOSA device for 20 min daily for 6 weeks. Objective sleep parameters were measured by a Watch-PAT, and use was tracked by the accompanying smartphone app. The time snoring greater than 40 dB (all snoring) was a primary outcome. Subjective decrease in snoring by the bed partner was measured by a Visual Analogue Scale (VAS), and the ESS and the 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.[28,] Patients with a body mass index (BMI) greater than 35 and AHI greater than 15 were excluded. Participants had a mean age of 46.45 and a mean BMI of 26.78 kg/m^2. For the 70 patients who completed the study, snoring time decreased by 48% and bed partners reported an average reduction of 40% in snoring. The mean AHI decreased from 5.94 to 5.37 events per hour. The PSQI improved by approximately 1 point for both the participants (7.03 [SD, 3.13] to 5.92 [SD, 2.83], p=.004) and bed partners (7.35 [SD, 2.76] to 6.33 [SD, 2.80], p=.029). In the 38 patients with mild OSA, AHI was reduced from 9.8 to 4.7 events per hour, and the ESS improved from 9.0 to 5.1 (p<.001). Compliance with the protocol, as measured by the app, ranged from 59.5% to 95.2% (mean utilization 83.3%).

Baptista et al (2021) reported the results of a study in which eXciteOSA was administered to 125 patients with a complaint of snoring and an AHI less than 15, 50 participants had an AHI of less than 5 and were considered primary snorers.[29,] Participants had a mean age of 45.71 and a mean BMI of 27.02 kg/m^2. Only 1 participant withdrew due to inability to tolerate the treatment, and 115 participants completed the trial (92%). The mean reduction in the proportion of time with moderate or greater snoring decreased from 30.41% to 17.87% (41% reduction, p<.001). Bed-partner-reported snoring decreased from 6.1 to 3.7 (p<.001). ESS improved from 8.4 to 5.8 and the PSQI improved for both the participants (7.16 to 5.75; 95% CI, 0.89 to 1.92; p <.001) and bed partners (6.87 to 5.94; 95% CI, 0.15 to 1.68; p =.02). The AHI was reduced from 6.85 to 5.01 (p<.001), a difference that is not clinically significant.

Nokes et al (2023) conducted a prospective study of 70 patients with mild obstructive sleep apnea (AHI range 5 to 15 events per hour) who were treated with eXciteOSA.[31,] Patients with a BMI greater than 35 were excluded. The median age was 49, and the median BMI was 27.7 kg/m^2. Five (7%) participants were excluded or withdrew prior to outcome assessment. The AHI decreased from 10.2 at baseline to 6.8 events/hour (p<.01) after treatment, and in the subset of 51 responders, the AHI decreased from 10.4 to 5.0 events per hour (p<.01). Objective snoring

time decreased from 36.5% to 21.5% (p<.01), and bed partner-reported snoring decreased from 6.3 to 3.9 on a visual analog scale (p<.01). The ESS improved from 8.7 to 5.3 points (p<.01), and the PSQI from 7.3 to 5.9 points (p<.01). Adherence with the device was 85% (range 57 to 100%), and adverse events were minor and transient.

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

Section Summary: Neuromuscular Electric Stimulation
One RCT and 5 prospective single-arm studies (3 with overlapping patient populations) have investigated the use of the eXciteOSA device for neuromuscular electrical stimulation in patients with primary snoring or mild obstructive sleep apnea (OSA). The RCT found high adherence to the device's treatment protocol, and exploratory analyses showed improvements in respiratory event index [RHI], apnea index, and hypopnea index relative to a sham control but no significant changes in Epworth Sleepiness Scale (ESS) scores. The study was limited by its small sample size and short follow-up period. The single-arm studies suggest that eXciteOSA may reduce snoring intensity and improve sleep quality, but the effects on the Apnea-Hypopnea Index (AHI) were mixed. Studies were limited to evaluations after the 6-week course of therapy or 2 weeks post-intervention. Larger, well-designed, controlled studies are needed to evaluate improvement in patients who meet the criteria for treatable OSA , to assess continued use after the 6-week trial period, and the durability of observed benefits.

NOVEL OBSTRUCTIVE SLEEP APNEA TREATMENTS

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

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

Populations
The relevant population is patients with OSA.

Interventions
The therapy being considered is novel OSA treatments (eg, 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.

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

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

Comparators

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

Outcomes

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

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

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

REVIEW OF EVIDENCE

PALATE AND MANDIBLE EXPANSION

Case Series
Singh et al (2016) reported on a series of 15 consecutive patients with severe sleep apnea who were treated with a DNA Appliance or mRNA Appliance.[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 ODI improved from 6.3% to 2.6% ($p<.001$). Limitations of these studies included the use of a home sleep apnea test rather than the more accurate laboratory polysomnography (PSG), uncertain blinding of the physician evaluating the sleep study, the small number of patients studied, lack of intention-to-treat (ITT) analysis, and lack of long-term follow-up.

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

Nonrandomized Comparative Study
Krakow et al (2008) reported on the use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP.[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.[25,] The most common risk factors for initial PAP rejection were depression, insomnia, claustrophobia, and trauma exposure, while the most common indications for PAP-NAP were general reluctance, anxiety, and claustrophobia. The procedure averaged about 3 hours, which included 83 + 30 min of coaching and 107 + 57 min napping; 99% of patients experienced

expiratory pressure intolerance and a majority preferred an alternative PAP mode for the nap period. Use at follow-up was determined by renewal request for PAP supplies, retitration, clinic appointment, or other contacts with staff. The duration of use is unclear from the report, but at the time of follow-up 71% of patients who had initially refused PAP were considered users and 29% were non-users.

NASAL EXPIRATORY POSITIVE AIRWAY PRESSURE

Systematic Reviews

A systematic review by Riaz et al (2015) identified 18 studies (N=920) that had data on pre-and postnasal EPAP.[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 (ODI) and percent of total sleep time with oxygen saturation <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduction to less than 10 events per hour (if device-off AHI was >10 events per hour), was greater in the EPAP group at 1 week (62% vs. 27.2%) and at 3 months (50.7% vs. 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and by 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing due to adverse events. Overall, the validity of these results was limited by the high dropout rate and uncertainty of the clinical significance of the results. Furthermore, the trial did not report the racial/ethnic composition of enrolled patients and enrolled mostly men.

Kryger et al (2011), in an open-label extension of the randomized study by Berry et al (2011), evaluated the 12-month safety and durability of the treatment response in patients who had an initially favorable response to EPAP.[28,] 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.[29,] 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).[30,] 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.

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.[33,] 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 6 and 7. The limitations of the trials are described in Tables 8 and 9.

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.[34,] 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.[35,] 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.[36,] 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 6. Summary of Key RCT Characteristics

Study	Countries	Sites	Design	Participants	Interventions	
					Active	**Comparator**
Eijsvogel et al (2015)[34,]	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)[35,]	EU	2	Randomized parallel arm	99 patients with mild to moderate POSA, defined as AHI > 2 times nonsupine AHI and total AHI < 15 events/hour	12 mo follow-up with NightBalance Sleep Position Trainer (n=48, 29 completed)	12 mo follow-up with OAT with an imbedded microchip to monitor usage (n=51, 29 completed)
Berry et al (2019)[36,] (POSAtive)	US	11	Randomized crossover	117 treatment-naive patients with exclusive POSA, defined as a supine AHI > 2 times nonsupine AHI and a nonsupine AHI < 10 events/hour; total AHI was at least 15 events/hour (moderate to severe OSA)	6 weeks with the NightBalance Sleep Position Trainer	6 weeks with APAP

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

Table 7. Summary of Key RCT Results

Study	AHI (SD)	Adherence (SD)	ESS (SD)	QOL (SD)
Eijsvogel et al (2015)[34,]		*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

Study	AHI (SD)	Adherence (SD)	ESS (SD)	QOL (SD)
p		.078		
de Ruiter et al (2018)[35,]	*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)[36,] (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 8. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Eijsvogel et al (2015)[34,]	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)[35,]	5. Racial/ethnic diversity of enrolled patients is not reported.				
Berry et al (2019)[36,] (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 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 9. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Eijsvogel et al (2015)[34,]	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)[35,]	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)[36,] (POSAtive)	3. Allocation concealment unclear	1, 2. Participants could not be blinded to treatment assignment.				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2.

Analysis is not appropriate for multiple observations per 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.[37,] 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. 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.[39,] 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.

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

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

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

2014 Input
In response to requests, input was received from 7 physician specialty societies (8 reviewers) and 4 academic medical centers (6 reviewers) while this policy was under review in 2014. Input focused on the routine screening of patients scheduled to undergo bariatric surgery. There was a consensus that routine screening is considered medically necessary in this population due to the high prevalence of obstructive sleep apnea (OSA) in patients with a body mass index greater than 40 kg/m^2, combined with the increased rate of perioperative complications in patients with OSA. The input was mixed on whether the use of portable home sleep testing was appropriate for patients scheduled for bariatric surgery. Concerns were raised about the high prevalence of obesity hypoventilation syndrome in this population, which is a contraindication to home sleep testing. Other reviewers considered home sleep testing to be appropriate in patients scheduled for bariatric surgery, with the caveat that obesity hypoventilation syndrome should be ruled out prior to home sleep testing.

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

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

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

American Academy of Otolaryngology-Head and Neck Surgery
In 2021, the American Academy of Otolaryngology-Head and Neck Surgery updated its position statement on the treatment of OSA.[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 Sleep Medicine
In 2017, the American Academy of Sleep Medicine (AASM) published clinical practice guidelines on diagnostic testing for adult OSA.[11,] AASM provided the following recommendations (Table 10).

Table 10. Recommendations on Diagnostic Testing for Adult OSA

Recommendation Statement	SOR	QOE	Benefits vs Harms
We recommend that clinical tools, questionnaires, and prediction algorithms not be used to diagnose OSA in adults, in the absence of PSG or HSAT	Strong	Moderate	High certainty that harms outweigh benefits
We recommend that PSG, or HSAT with a technically adequate device, be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA.	Strong	Moderate	High certainty that benefits outweigh harms
We recommend that if a single HSAT is negative, inconclusive, or technically inadequate, PSG be performed for the diagnosis of OSA.	Strong	Low	High certainty that benefits outweigh harms
We recommend that PSG, rather than home sleep testing, be used for patients with significant cardiorespiratory disorder, potential respiratory muscle weakness, awake or suspected sleep hypoventilation, chronic opioid medication use, history of stoke or severe insomnia.	Strong	Very low	High certainty that benefits outweigh harms
We suggest that, if clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for PSG be used for the diagnosis of OSA	Weak	Low	Low certainty that benefits outweigh harms

Recommendation Statement	SOR	QOE	Benefits vs Harms
We suggest that when the initial PSG is negative, and there is still clinical suspicion for OSA, a second PSG be considered for the diagnosis of OSA.	Weak	Very low	Low certainty that benefits outweigh harms

HSAT: home sleep apnea testing; OSA: obstructive sleep apnea; PSG: polysomnography; QOE: quality of evidence; SOR: strength of recommendation.

Diagnosis

The AASM considers a technically adequate home sleep apnea test (HSAT) device to incorporate "a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else PAT [peripheral arterial tone] with oximetry and actigraphy." The guidelines refer to the AASM Manual for the Scoring of Sleep and Associated Events for additional information regarding HSAT sensor requirements.

In 2021, the AASM published a guidance statement that focuses on indications for follow-up sleep apnea testing with PSG or home sleep apnea tests in patients with OSA.[12,] The following clinical guidance statements were provided:

- "Follow-up PSG or HSAT is not recommended for routine reassessment of asymptomatic patients with obstructive sleep apnea on PAP therapy, however, follow-up PSG or HSAT can be used to reassess patients with recurrent or persistent symptoms, despite good PAP [positive airway pressure] adherence.
- Follow-up PSG or HSAT is recommended to assess response to treatment with non-PAP interventions.
- Follow-up PSG or HSAT may be used if clinically significant weight gain or loss has occurred since diagnosis of OSA or initiation of its treatment.
- Follow-up PSG may be used for reassessment of sleep-related hypoxemia and/or sleep-related hypoventilation following initiation of treatment for OSA.
- Follow-up PSG or HSAT may be used in patients being treated for OSA who develop or have a change in cardiovascular disease.
- Follow-up PSG may be used in patients with unexplained PAP device-generated data."

The AASM also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA.[13,] 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 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.[14,15,] AAP recommended that all children or adolescents be screened for snoring, and PSG is performed in children or adolescents with snoring and symptoms or signs of OSA as listed in the guideline. If PSG is not available, an alternative diagnostic test or referral to a specialist may be considered (option). The estimated prevalence rates of OSA in children or adolescents ranged from 1.2% to 5.7%.

Adenotonsillectomy was recommended as the first-line treatment for patients with adenotonsillar hypertrophy, and patients should be reassessed clinically postoperatively to determine whether additional treatment is required. High-risk patients should be reevaluated with an objective test or referred to a sleep specialist. CPAP was recommended if adenotonsillectomy was not

performed or if OSA persisted postoperatively. Weight loss was recommended in addition to other therapy in patients who are overweight or obese, and intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

American Society of Metabolic and Bariatric Surgery
The American Society of Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA (reviewed in October 2015).[16,] 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.[45,] 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.

American Heart Association
In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease.[17,] The treatment options for OSA and eligibility for their use are described in the statement.

Recommendations for screening for OSA are as follows:

- "We recommend screening for OSA in patients with resistant/poorly controlled hypertension, pulmonary hypertension, and recurrent atrial fibrillation after either cardioversion or ablation."

- "In patients with New York Heart Association class II to IV heart failure and suspicion of sleep-disordered breathing or excessive daytime sleepiness, a formal sleep assessment is reasonable."
- "In patients with tachy-brady syndrome or ventricular tachycardia or survivors of sudden cardiac death in whom sleep apnea is suspected after a comprehensive sleep assessment, evaluation for sleep apnea should be considered."
- "After stroke, clinical equipoise exists with respect to screening and treatment."

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."

National Institute for Health and Care Excellence
NICE provides guidance on medical management in individuals with varying degrees of OSA.[55,] They recommend offering fixed-level CPAP in those with mild OSA when symptoms affect QOL and usual daytime activities if lifestyle changes alone have been unsuccessful or are considered inappropriate. They recommend APAP as an alternative to fixed-level CPAP in those unable to tolerate CPAP. In individuals who cannot tolerate or refuse CPAP, they recommend offering a customized mandibular advancement device. In individuals with moderate to severe OSA, CPAP is recommended as a treatment option, with APAP offered as an alternative in those unable to tolerate CPAP. Similarly, a customized mandibular advancement device may be used if an individual refuses PAP or is unable to tolerate PAP. NICE also states that a positional modifier may be considered for those with mild to moderate positional OSA if other treatments are unsuitable or not tolerated, but this should not be a first-line treatment option.

NICE published guidance on daytime intraoral neuromuscular electrical tongue stimulation for obstructive sleep apnea in 2023.[56,] A rapid review of evidence identified 1 single-arm trial and 1 pilot study and also considered 2 submissions from patient organizations about the procedure. NICE recommended that the procedure should only be used in a research setting due to an inadequate quantity and quality of evidence and that further adequately powered RCTs and analysis of observational data should be used to assess efficacy, safety, and adherence.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (2022) reported on the evidence for screening for OSA in adults and concluded that "the current evidence is insufficient to assess the balance of benefits and harms of screening for obstructive sleep apnea in the general adult population. Evidence on screening tools to accurately detect persons in the general adult population at increased risk of OSA who should receive further testing and treatment is lacking".

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in April 2024 identified over 200 ongoing studies on the diagnosis and medical management of OSA.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
94762	Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811	Polysomnography; ; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)

CPT/HCPCS	
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
E0490	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0491	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous airway pressure (CPAP) device
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment

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01-01-2011	In Title: ▪ Policy title changed from "Polysomnography and Sleep Studies" to "Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome"
	Description section updated
	In policy section: ▪ Revised wording to current medical policy wording from: "BCBSKS encourages sleep study facilities to become accredited through the American Academy of Sleep Medicine (AASM) and/or the Accreditation Commission for Health Care, Inc. (ACHC) and physicians to be board certified in sleep medicine. The following criteria and documentation for medical necessity applies to all providers, regardless of their accreditation or certification level. Polysomnography is indicated: ▪ for diagnosis of sleep related breathing disorders,

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	▪ for continuous positive airway pressure (CPAP) titration in patient's sleep related breathing disorders, ▪ for documenting the presence of obstructive sleep apnea for patients prior to surgical interventions, ▪ for the assessment of treatment results in some cases, ▪ with a multiple sleep latency test in the evaluation of suspected narcolepsy, ▪ in evaluating sleep related behaviors that are injurious, and ▪ in certain atypical or unusual parasomnias Medically necessary indications for polysomnography for adults include one or more of the following: 1. Witnessed apnea during sleep; OR 2. Any combination of two or more of the following (a through d): a. Excessive daytime sleepiness as evidenced by one or more of the following: ▪ Inappropriate daytime napping (e.g., during driving, conversation, or eating); ▪ Sleepiness that interferes with daily activities; (The following should be ruled out as a cause for these symptoms: poor sleep hygiene, medication, drugs, alcohol, hypothyroidism, other medical diagnoses, psychiatric, or psychological disorders, social or work schedule changes.) ▪ An Epworth Sleepiness Scale score greater than 10; or b. Persistent or frequent socially disruptive snoring; or c. Obesity (BMI greater than 30 kg/m2) or hypertension; or d. Choking or gasping episodes associated with awakening. OR 3. Symptoms suggesting narcolepsy, e.g., sleep paralysis, hypnagogic hallucinations, cataplexy; OR 4. Violent or injurious behavior during sleep; OR 5. Other situations (if nocturnal pulse oximetry suggests nocturnal oxygen desaturation) such as ▪ Unexplained right heart failure; ▪ Unexplained polycythemia; ▪ Presence of or increase in cardiac arrhythmias during sleep; ▪ Unexplained pulmonary hypertension. OR 6. Excessive daytime sleepiness together with witnessed periodic limb movements of sleep; OR 7. Unusual or atypical parasomnias based on patient's age, frequency, or duration of behavior; OR 8. Patients with moderate or severe congestive heart failure, stroke/TIA, coronary artery disease, or significant tachycardic or bradycardic arrhythmias who have nocturnal symptoms suggestive of a sleep related breathing disorder or otherwise suspected of having sleep apnea. Repeat standard polysomnography for adults is considered medically necessary under the following circumstances: 1. Failure of resolution of symptoms or recurrence of symptoms during treatment; OR 2. Post-operatively following uvulopalatopharyngoplasty (UPPP) or other corrective surgeries for obstructive sleep apnea (due to the variable outcome of these surgical procedures); OR 3. Following treatment with an oral appliance for obstructive sleep apnea with an apnea hypopnea index (an AHI) or respiratory disturbance index (RDI) of >15 pre-treatment to ensure effective treatment; OR 4. To titrate CPAP following an initial polysomnography where obstructive sleep apnea was demonstrated and a split night study was not feasible; OR

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	5. To reevaluate the diagnosis of obstructive sleep apnea and need for continued CPAP in a patient previously diagnosed by polysomnography and currently using CPAP, if a significant weight loss has occurred since the initial study. Not Medically Necessary: <u>Two Separate Night Studies</u> Two separate nights' polysomnography studies, one for the diagnosis of sleep disorders and the second to titrate CPAP, are generally considered not medically necessary unless circumstances do not allow for half night or "split night" polysomnography with titration of CPAP performed in the second part of the study, (e.g., significant obstructive sleep apnea, [that is with an AHI or RDI of 20 or more with oxygen desaturations], not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep). In these cases, a second full night's study may then be medically necessary for CPAP titration. <u>Repeat Standard Polysomnography</u> Repeat polysomnography is considered not medically necessary in the follow-up of patients with obstructive sleep apnea treated with CPAP when symptoms attributable to sleep apnea have resolved. Polysomnography is not routinely indicated: ▪ to diagnose or treat restless legs syndrome, ▪ for the diagnosis of circadian rhythm sleep disorders, ▪ to establish a diagnosis of depression, ▪ for the following conditions existing alone in the absence of other features suggestive of obstructive sleep apnea: Snoring, obesity, hypertension, morning headaches, decrease in intellectual functions, memory loss, frequent nighttime awakenings, other sleep disturbances, such as insomnia (acute or chronic), night terrors, sleep walking, epilepsy where nocturnal seizures are not suspected, common uncomplicated non-injurious parasomnias Unattended (unsupervised) sleep studies are considered experimental / investigational. DOCUMENTATION Prior to performing a sleep study, the sleep laboratory's Medical Director or physician should ascertain that the following have been completed and establish the medical necessity of the test. It is expected that the sleep laboratory will either assess the information from the ordering physician or acquire the information and document it so that medical necessity is well established or indicate why an exception is valid. Either ordering physician or sleep lab physician must sign off that these steps have been documented and evaluated prior to sleep study. This information should be kept on file for medical necessity reviews and audit purposes. 1. History and physical/sleep related symptoms, significant medical conditions, medical findings, medications, allergies, and personal habits that could affect the sleep status (i.e., alcohol consumption, psychiatric condition) should be included. Such things as a two week sleep diary may have been completed. An assessment should be made and signed by the ordering physician, and must be reviewed by the sleep laboratory or obtained by the sleep laboratory physician, in order to establish the appropriate testing and medical necessity. The history should also document an effort to screen for the possibility of depression. 2. A sleep evaluation questionnaire (mini survey), such as the Berlin questionnaire, should have been completed and assessed by the ordering physician and/or the sleep laboratory (standard questionnaire if information is not included in #1 above). 3. A sleepiness scale, such as an Epworth scale, should have been completed. Once again, the sleep laboratory is to ascertain that the sleepiness scale fits with a clinical picture that would establish medical necessity.

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	4. There is an expectation that potential therapeutic options have been discussed thoroughly with the patient and potential compliance issues have been addressed. This should have been done by the ordering physician or by the sleep laboratory physician. It is also the expectation that the sleep laboratory will determine the individual education needs of the patient and will provide this education (i.e., CPAP therapy)." ▪ Policy Guidelines added
	Rationale section added
	In Coding section: ▪ Removed CPT Codes: 0203T, 0204T ▪ Added CPT Codes: 94660, 94762, 95800, 95801 ▪ Added HCPCS Codes: A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, E0470, E0471, E0485, E0486, E0561,E0562, E0601 ▪ Removed Diagnosis Codes: 327.24, 327.27, 770.81, 780.09, 780.52, 780.55, 780.56 ▪ Added Diagnosis Codes: 327.10, 327.11, 327.13, 327.29 ▪ Correct 347 to reflect: 347.00, 347.01, 347.10, 347.11
	References section updated
01-12-2011	In Policy section: ▪ Removed from II B 2 the following wording as it was erroneously listed in the pediatric section of the policy, "(e.g., significant obstructive sleep apnea, [that is with an AHI or RDI of 20 or more with oxygen desaturations], not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep)."
02-25-2011	In Policy section: ▪ Removed the word "Titration" from I. B. and II. B. entitled CPAP Titration to read "CPAP". ▪ Corrected an error in Policy Guidelines #1, by removing "and an associated fall in oxygen saturation of at least 4%." from the sentence "An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort and an associated fall in oxygen saturation of at least 4%." to read "An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort." ▪ Corrected an error in Policy Guidelines #1 by changing "…4% oxygen desaturation." to "…3% oxygen desaturation."
08-30-2012	Description section updated
	In Policy section: ▪ Revised policy sections from "I. Adults – 18 and over" and "II. Children – under 18" to "I. Diagnosis" and "II. Medical Management" and reformatted the indications to fall under each respectively. ▪ In I A 1 b c) added "(this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children)" to read "sleepiness that interferes with daily activities and is not explained by other conditions (this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children)" ▪ In I A 1 b 4) added "or greater than the 90th percentile for the weight/height ratio in pediatric patients," to read "Obesity, defined as a body mass index greater than 30 kg/m2 in adults or greater than the 90th percentile for the weight/height ratio in pediatric patients," ▪ Moved the pediatric supervised polysomnography indications from the prior Pediatric section to become I A 1 i under the new Diagnosis section (no change in indications) ▪ In I B 1 c added "severe" to the unattended (unsupervised) Home Sleep Studies indication of chronic pulmonary disease to read, "Severe chronic pulmonary disease"

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	▪ In I B 2 added "and in pediatric patients" to read, "Unattended (unsupervised) sleep studies are considered experimental / investigational in adult patients who are considered at low to moderate risk for OSA and in pediatric patients." ▪ In I C Repeat Supervised Polysomnography added, "1. To initiate and titrate continuous positive airway pressure (CPAP) in adult patients with clinically significant OSA defined as those patients who have: a. An apnea/hypopnea index (AHI) of at least 15 per hour, OR b. An AHI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension. Note: ▪ In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 is considered severe. ▪ A split-night study, in which severe OSA is documented during the first portion of the study using polysomnography, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines for criteria to perform a split-night study)." ▪ Removed from I E "[that is with an AHI or RDI of 20 or more with oxygen desaturations]," to read "e.g., significant obstructive sleep apnea, [that is with an AHI or RDI of 20 or more with oxygen desaturations], not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep)." ▪ Added the new medically necessary indication of "II B Bilevel positive airway pressure or auto-adjusting CPAP may be considered medically necessary in patients with clinically significant OSA AND who have failed a prior trial of CPAP or for whom BiPAP is found to be more effective in the sleep lab." ▪ Revised Intraoral Appliances from "Intraoral appliances* may be considered medically necessary in patients with clinically significant OSA, as defined in Policy Guidelines. *Intraoral appliances include either tongue-retaining devices or mandibular advancing/positioning devices." to "Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in patients with clinically significant OSA under the following conditions: 1. OSA, defined by an apnea/hypopnea index (AHI) of at least 15 per hour or an AHI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension, AND 2. The device is prescribed by a treating physician, AND 3. The device is custom-fitted by qualified dental personnel. AND Note: 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, as oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-moderate OSA. Therefore, it is particularly important that patients with severe OSA should 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." ▪ Added the new experimental / investigational indication of "A nasal expiratory positive airway pressure (EPAP) device is considered experimental / investigational." ▪ Policy Guidelines updated
	Rationale section updated
	In Coding section: ▪ Add HCPCS Code: E1399
	References updated
01-01-2013	In Coding section: ▪ Added CPT codes: 95782, 95783 (effective 01-01-2013)

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	▪ Revised nomenclature on CPT code: 95808, 95810, 95811 (effective 01-01-2013)
09-16-2015	Description section updated
	Rationale section updated
	In Coding section: • HCPCS Code Removed: E1399 • Coding instructional information updated. • ICD-10 Codes added.
	References updated
01-01-2020	Policy published 12-02-2019. Policy effective 01-01-2020.
	Description section updated
	In Policy section: Policy changes in summary are: Diagnosis-Home Sleep Apnea Test • include new terminology of home sleep apnea test versus home sleep studies • revising health conditions when home sleep apnea test is not eligible • clarify that devices include a minimum of 3 sensors • add medical necessity for unattended home sleep apnea test as a screening tool in patient who are scheduled for bariatric surgery when criteria are met Diagnosis-Supervised Polysomnography • revised eligibility criteria to when home sleep apnea test criteria is not met • revised presence of comorbidity eligibility • re-defined AHI, RDI, and REI criteria • removed Two Separate Night Studies criteria • added PAP-NAP E/I statement Medical Management ▪ added auto-adjusting medical necessity and criteria ▪ updated intraoral appliances criteria ▪ added palate, mandible expansion and oral pressure therapy devices E/I statements Policy changed to the current policy from the following: "I. Diagnosis A. Supervised Polysomnography 1. Supervised polysomnography performed in a sleep laboratory may be considered medically necessary as a diagnostic test in patients with any of the following: a. Observed apneas during sleep OR b. A combination of at least 2 of the following: 1) Excessive daytime sleepiness evidenced by: a) an Epworth Sleepiness Scale greater than 10 b) inappropriate daytime napping (e.g., during driving, conversation, or eating), or c) sleepiness that interferes with daily activities and is not explained by other conditions (this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children) 2) Habitual snoring, or gasping/choking episodes associated with awakenings, 3) Unexplained hypertension, 4) Obesity, defined as a body mass index greater than 30 kg/m2 in adults or greater than the 90th percentile for the weight/height ratio in pediatric patients,

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	5) Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, 6) Neuromuscular disease OR c. Moderate or severe congestive heart failure, stroke/transient ischemic attack, coronary artery disease, or significant tachycardia or bradycardic arrhythmias in patients who have nocturnal symptoms suggestive of a sleep-related breathing disorder or otherwise are suspected of having sleep apnea OR d. Symptoms suggesting narcolepsy, e.g., sleep paralysis, hypnagogic hallucinations, cataplexy OR e. Violent or injurious behavior during sleep OR f. Other situations (if nocturnal pulse oximetry suggests nocturnal oxygen desaturation) such as: 1) Unexplained right heart failure 2) Unexplained polycythemia 3) Presence of or increase in cardiac arrhythmias during sleep 4) Unexplained pulmonary hypertension OR g. Excessive daytime sleepiness together with witnessed periodic limb movements of sleep OR h. Unusual or atypical parasomnias based on patient's age, frequency, or duration of behavior OR i. Pediatrics – under 18 – with ANY of the following additional indications: 1) behavioral problems, which may be expressed as: a) learning difficulties OR b) daytime neurobehavioral problems in young children OR 2) hyperactivity OR 3) snoring alone OR 4) chronic disturbed sleep Risk factors include: ▪ adenotonsillar hypertrophy ▪ obesity (defined as greater than the 90th percentile for the weight/height ratio) ▪ craniofacial anomalies, and ▪ neuromuscular disorders 2. Routine supervised polysomnography is not medically necessary for the following: a. To diagnose or treat restless legs syndrome b. To establish a diagnosis of depression c. For the following conditions existing alone in the absence of other features suggestive of obstructive sleep apnea: 1) Snoring 2) Obesity 3) Hypertension 4) Morning headaches 5) Decrease in intellectual functions 6) Memory loss 7) Frequent nighttime awakenings 8) Other sleep disturbances, such as insomnia (acute or chronic), night terrors, sleep walking, epilepsy where nocturnal seizures are not suspected 9) Common uncomplicated non-injurious parasomnias B. Unattended (unsupervised) Home Sleep Studies

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	1. Unattended (unsupervised) home sleep studies with a minimum of 4 recording channels (2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation) may be considered medically necessary in adult patients who are at risk for OSA and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including the following: a. Central sleep apnea b. Congestive heart failure c. Severe chronic pulmonary disease d. Obesity hypoventilation syndrome e. Narcolepsy f. Periodic limb movements in sleep g. Restless leg syndrome Note: Respiratory disturbance index may be used in place of apnea/hypopnea index (AHI) in unattended sleep studies. 2. Unattended (unsupervised) sleep studies are considered experimental / investigational in pediatric patients. C. Repeat Supervised Polysomnography A repeat supervised polysomnography performed in a sleep laboratory may be considered medically necessary under the following circumstances: 1. To initiate and titrate continuous positive airway pressure (CPAP) in adult patients with clinically significant OSA defined as those patients who have: a. An apnea/hypopnea index (AHI) of at least 15 per hour, OR b. An AHI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension. Note: ▪ In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 is considered severe. ▪ A split-night study, in which severe OSA is documented during the first portion of the study using polysomnography, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines for criteria to perform a split-night study). OR 2. Failure of resolution of symptoms or recurrence of symptoms during treatment OR 3. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices OR 4. To re-evaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued Note: This statement does not imply that supervised studies are needed routinely following unattended studies. This statement means a re-evaluation based on a substantial change in symptoms or in the clinical situation. D. Repeat Unattended (unsupervised) Home Sleep Studies Repeat unattended (unsupervised) home sleep studies with a minimum of four recording channels (2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation) may be considered medically necessary in adult patients under the following circumstances: 1. To assess efficacy of surgery or oral appliances/devices; OR

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	2. To re-evaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued. E. Two Separate Night Studies Two separate nights' polysomnography studies, one for the diagnosis of sleep disorders and the second to titrate CPAP, are generally considered not medically necessary unless circumstances do not allow for half night or "split night" polysomnography with titration of CPAP performed in the second part of the study, (e.g., significant obstructive sleep apnea not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep). In these cases, a second full night's study may then be medically necessary for CPAP titration. F. Multiple Sleep Latency Testing Multiple sleep latency testing is considered not medically necessary in the diagnosis of OSA except to exclude or confirm narcolepsy in the diagnostic workup of OSA syndrome. II. Medical Management A. CPAP CPAP may be considered medically necessary in adult patients with clinically significant OSA defined as: 1. Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour, OR 2. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke, OR 3. For pediatric patients: a. AHI or RDI of at least 5 per hour, or b. AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity. Note: AHI greater than 1.5 is considered abnormal, and AHI of 15 or more is considered severe. B. Bilevel positive airway pressure or auto-adjusting CPAP may be considered medically necessary in patients with clinically significant OSA AND who have failed a prior trial of CPAP or for whom BiPAP is found to be more effective in the sleep lab. C. Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in patients with clinically significant OSA under the following conditions: 1. OSA, defined by an apnea/hypopnea index (AHI) of at least 15 per hour or an AHI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension AND 2. The device is prescribed by a treating physician AND 3. The device is custom-fitted by qualified dental personnel. Note: 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, as oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-moderate OSA. Therefore, it is

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	particularly important that patients with severe OSA should 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. D. A nasal expiratory positive airway pressure (EPAP) device is considered experimental / investigational.
	Rationale section updated
	In Coding section: ▪ Added CPT Code: A7002 ▪ Added ICD-10 Codes: G47.8, G47.9, R06.81
	References updated
04-16-2021	Description section updated
	Rationale section updated
	References updated
06-21-2021	The following changes were made to the Policy section based on recommendations from the Dental Advisory Committee. Item II.D.4 • Added "a dentist or by" and "under the supervision of a dentist" Item II.D.5 • Replaced "There is absence of temporomandibular dysfunction or periodontal disease" with "The patient has been cleared by a dentist"
10-01-2021	In Coding section Added HCPCS code: K1027 Effective 10-01-2021
04-01-2022	Updated Coding Section Added K1028, K1029
09-08-2022	Updated Description Section
	Updated Policy Section ▪ Formatted section with A.1.a.I.i. Format ▪ Removed A4 under Diagnosis: "The use of an abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies is considered experimental / investigational" ▪ Added the following statements under B Medical Management: 6. "The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered experimental / investigational." 7. " The use of a sleep positioning trainer with vibration is considered experimental / investigational for the treatment of positional OSA." 8. "The use of daytime electrical stimulation of the tongue is considered experimental / investigational for the treatment of OSA."
	Updated Policy Guideline Section ▪ Removed "male gender" from statement B "Risk Factors for Obstructive Sleep Apnea"
	Updated Rationale Section
	Updated Coding Section ▪ Removed: A7032, A7033, A7044, A7045, A7002, A7027, A7028, A7029, A7030, A7031, A7034, A7035, A7036, A7037, A7038, A7039, E1399 ▪ Added: K1001 ▪ Removed coding bullets <u>Attended Studies</u> CPT Codes: 95807, 95808, 95810, 95811, 95782, 95783. <u>Unattended Study</u>

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	CPT Codes: 95806 (Note that this CPT code is identical to 95807 except that the study is not monitored.) 95800, 95801 (These differ from 95806 in the description of a single respiratory sensor [either air flow or peripheral arterial tone] instead of the standard configuration of both respiratory effort and respiratory airflow [ventilation]). Use of overnight oximetry alone would be indicated by CPT code 94762. HCPCS Codes There is 1 HCPCS code identifying a CPAP device, E0601, and 2 HCPCS codes for BiPAP devices: E0470 and E0471. The HCPCS codes do not distinguish among fixed CPAP or BiPAP devices and auto-adjusting CPAP devices. In 2008, Medicare created G codes to facilitate their national coverage decision: G0398, G0399, G0400. There is a HCPCS code for the oral interface used with devices such as the Winx system: A7047. The system would be reported using code E0600 (Respiratory Suction Pump, Home Model, Portable or Stationary, Electric) and code A7002 (Tubing, Used with Suction Pump, Each).
	Updated References Section
07-25-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Codes
	Updated References Section
10-02- 2023	Updated Coding Section ▪ Added: E0490 and E0491 (eff. 10-01-2023) ▪ Updated nomenclature for K1028
01-01-2024	Updated Coding Section ▪ Added E0492, E0493 and E0530 (eff. 01-01-2024) ▪ Removed Deleted codes K1001, K1028 and K1029 (eff. 01-01-2024)
07-23-2024	Updated Description Section
	Updated Policy Section ▪ Removed from B8: "daytime" and "of the tongue" Now reads "The use of neuromuscular electrical tongue stimulation is considered experimental / investigational for the treatment of OSA."
	Updated Rationale Section
	Updated References Section

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