Policy Statement

Diagnosis

Unattended (Unsupervised) Home Sleep Apnea Test
Blue Shield of California (BSC) requires an unattended (unsupervised) home sleep apnea test (HSAT) as the initial study for the screening for and diagnosis of moderate to severe (see Policy Guidelines section) obstructive sleep apnea (OSA) in adults unless contraindicated.

A home sleep apnea test for suspected mild OSA (not meeting criteria for moderate to severe, except before bariatric surgery) is considered not medically necessary.

A home sleep apnea test may be considered medically necessary as a screening tool in patients who are scheduled for bariatric surgery and have no contraindications.

Contraindications to home sleep studies include, but are not limited to significant, ongoing symptoms (see Policy Guidelines section) related to:
- Central sleep apnea
- Symptomatic heart failure
- Symptomatic chronic pulmonary disease
- Obesity hypoventilation syndrome (see Policy Guidelines section)
- Neuromuscular disorders with sleep-related symptoms (see Policy Guidelines section)
- Stroke or recurrent Transient Ischemic Attacks (TIAs)
- Coronary Artery Disease
- Tachycardic or bradycardic arrhythmias
- Injurious or potentially injurious parasomnias
- Narcolepsy

Note: A home sleep apnea test should include one of the following (see Policy Guidelines section):
- A minimum of 3 recording channels with the following sensors:
  - Nasal pressure
  - Chest and abdominal respiratory inductance plethysmography
  - Oximetry (see Policy Guidelines section)
- Peripheral Arterial Tone (PAT) with oximetry and actigraphy
- A minimum of 4 recording channels with the following sensors:
  - Oximetry
  - Respiratory movement (respiratory effort belt)
  - Airflow
  - Electrocardiogram (ECG) or heart rate

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

Unattended home sleep apnea tests are considered investigational in children (younger than 18 years of age).

Repeated unattended (unsupervised) home sleep apnea tests meeting the technical requirements noted above may be considered medically necessary in adult patients under either of the following circumstances:
• To assess efficacy of surgery or oral appliances/devices
• To reevaluate the diagnosis of OSA and need for CPAP (e.g., if there is a significant
decrease in weight [see Policy Guidelines] or symptoms suggesting that CPAP could be
discontinued; or if there has been a significant increase in weight with continued or
worsening symptoms when an earlier study did not show OSA)

Supervised or unattended home sleep apnea tests that do not meet the above criteria are
considered not medically necessary, including but not limited to the use of devices (Type 3 or 4)
using less than the channels required above.

**Supervised Polysomnography (PSG) in a Sleep Laboratory**

An initial or repeat supervised polysomnography (PSG) performed in a sleep laboratory may be
considered medically necessary in patients with a moderate or high pretest probability of OSA in
any of the following situations:

• Pediatric patients (i.e., less than 18 years of age)
• To initiate and titrate CPAP in adult patients who have clinically significant OSA*
• A previous home study failed to establish the diagnosis of OSA in a patient with a high
pretest probability of OSA
• A previous home study was technically inadequate
• Failure of resolution of symptoms or recurrence of symptoms during treatment
• To assess efficacy of surgery or oral appliances/devices if a home sleep study could not
confirm or disprove OSA
• To assess efficacy of adenotonsillectomy in patients under the age of 18
• To initiate and titrate CPAP in children with either of the following:
  o An AHI or RDI of greater than or equal to 5 events per hour
  o An AHI or RDI greater than or equal to 1.5 events per hour in a patient with excessive
daytime sleepiness, behavioral problems, or hyperactivity
• Presence of a known comorbidity that might alter ventilation or decrease the accuracy
of a home sleep apnea test, including, but not limited to significant, ongoing symptoms
(see Policy Guidelines section) of central sleep apnea, heart failure, chronic pulmonary
disease, obesity hypoventilation syndrome, neuromuscular disorders, stroke/recurrent
transient ischemic attack, coronary artery disease, tachycardic or bradycardic
arhythmias
• After OSA has been treated or ruled out, when testing is done to look for other sleep
disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or
narcolepsy (often done prior to multiple sleep latency testing; see also Medical Policy:
Polysomnography for Non-Respiratory Sleep Disorders)
• To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried
and failed

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

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

The use of an abbreviated daytime sleep apnea test (PAP-NAP) as a supplement to standard
sleep studies is considered investigational.

Multiple sleep latency testing (MSLT) is considered not medically necessary in the initial workup of
OSA.** A PSG in a sleep lab is usually done before an MSLT when done to look for narcolepsy if
OSA has already been treated or ruled out.
Medical Management

CPAP may be considered medically necessary in adult or pediatric patients with clinically significant OSA, provided that diagnosis was based on the performance of an approved three-channel (or greater) diagnostic study.

Replacement of a PAP device after the warranty period (usually 2-5 years) requires documentation that the device is no longer functioning properly or another reason for replacement, current compliance prior to the problem with the machine, and benefit from the device. If within the warranty period, documentation is also needed that the cost of repairs would exceed that of replacement. A repeat sleep apnea test or trial period is not required if prior test results showing the need for CPAP is provided (see Policy Guidelines section for definition of compliance).

Bilevel positive airway pressure (BiPAP) or APAP may be considered medically necessary in patients with both of the following:

- Clinically significant OSA
- One of the following:
  - Who have failed a prior trial of CPAP
  - Whom BiPAP is found to be more effective in the sleep lab

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in adults with clinically significant OSA when all of the following conditions have been met:

- Initial or continued use of CPAP is clinically not indicated or is refused by the patient
- The device is prescribed by a treating physician
- The device is custom-fitted by qualified dental personnel
- There is documentation of absence of significant temporomandibular dysfunction or periodontal disease

Replacement of an oral appliance (OA) after the warranty period (usually 3 years) requires documentation of the need for replacement (including, but not limited to quality photographic evidence), current compliance prior to the problem with the device (see Policy Guidelines section below), and benefit from the use of the OA. If during the warranty period, documentation is also needed that the cost of repairs exceeds that of replacement.

Replacement of an oral appliance due to changes in dental alignment for orthodontic treatment is considered not medically necessary unless it is needed after completion of treatment prescribed and supervised by an orthodontist, and all the other medically necessary requirements as noted above are met for replacement.

A repeat sleep apnea test is not required if prior test results showing the need for the device is provided.

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, because oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-to-moderate OSA. Therefore, it is particularly important that patients with severe OSA have an initial trial of CPAP and that all reasonable attempts are made to continue treatment with CPAP, prior to the decision to switch to an oral appliance.

Nasal expiratory positive airway pressure, oral pressure therapy devices, and mandibular/palatal expansion devices for the treatment of OSA are considered investigational.
Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

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

**See Blue Shield of California Medical Policy: Polysomnography for Non-Respiratory Sleep Disorders

Policy Guidelines

Home Sleep Apnea Test Devices
American Academy of Sleep Medicine (AASM) updated their guidelines in 2019 to recommend devices using BOTH a respiratory and abdominal belt (dual belt). Heart rate is no longer required. In addition, devices using PAT technology (e.g., WatchPAT) are also recommended. Since many existing devices (such as many 4 channel devices) will not meet these criteria, the previous standard 4 channel tests will be allowed during a period of transition. A standard 4 channel HSAT uses CPT code 95806. The WatchPAT device uses CPT code 95800.

New devices using 2 respiratory effort belts should use CPT code G0400 since there is no heart rate. Code 95801 should not be used since it does not have the required types of channels.

Oximetry may be noted by the terms pulse oximetry (SpO2), oxygen saturation or CO-oximetry (measures carbon monoxide [CO] in addition to oxygen saturation).

Definition of Obstructive Sleep Apnea
Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep.

The following are generally accepted measures of OSA severity:
  - None/minimal: AHI, RDI, or REI less than 5 events/hour
  - Mild: AHI, RDI, or REI greater than or equal to 5 events/hour but less than 15 events/hour
  - Moderate: AHI, RDI, or REI greater than or equal to 15 events/hour but less than 30 events/hour
  - Severe: AHI, RDI, or REI greater than or equal to 30 events/hour

Hypertension
Systolic BP ≥140 or diastolic BP ≥90, or on current medical treatment for hypertension.

Risk Factors for Obstructive Sleep Apnea
Although not an exclusive list, patients with any two of the following symptoms are considered to have a moderate-to-high probability for moderate to severe OSA:
  - Habitual snoring
  - Observed apneas
  - Excessive daytime sleepiness
  - A body mass index (BMI) greater than 35 kg/m²

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

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

Obesity-Hypoventilation Syndrome
Defined as daytime alveolar hypoventilation (awake arterial $P_{CO_2} > 45$ mm Hg or serum bicarbonate $\geq 27$) among patients with body mass index $\geq 30$ kg/m$^2$ in the absence of other causes of hypoventilation.

Neuromuscular Diseases Contraindicating Home Sleep Studies
- Amyotrophic lateral sclerosis (ALS)
- Charcot-Marie-Tooth disease
- Multiple sclerosis
- Muscular dystrophy
- Myasthenia gravis
- Myopathy, severe
- Myositis, including polymyositis and dermatomyositis
- Peripheral neuropathy, severe
- Spinal muscular atrophy

Sleep Questionnaires
The following sleep questionnaires (all self-answered by the patient) attempt to quantify the probability of having OSA:
- Epworth Sleepiness Scale: Comprised of eight questions with a maximum score of 24. A score of greater than 10 indicates moderate to high probability of OSA.
- Berlin Questionnaire: Comprised of 10 questions and three scoring categories. Two or more positive categories indicate a high probability of OSA.
- STOP-BANG: Comprised of eight questions. A “yes” answer on three or more questions indicates a high probability of OSA. The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender) and has been shown to have 97% sensitivity and a negative predictive value of 96% (specificity of 33%) for the identification of patients with severe OSA (Apnea/Hypopnea Index [AHI] score greater than 30 events per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is inadequate for the diagnosis of OSA. Therefore, a follow-up polysomnography (PSG) or home sleep apnea test would still be required to confirm or exclude a diagnosis of OSA.

Obstructive Sleep Apnea in Children
The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a BMI greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI or RDI greater than 1.5 events per hour is considered abnormal (an AHI or RDI greater than or equal to 10 events per hour may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. Continuous positive airway pressure (CPAP) is an option for children who are not candidates for surgery or who have an inadequate response to surgery.
Bariatric Surgery Patients
Screening for OSA should be performed routinely in patients 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 apnea test is the most accurate screening method. Some experts recommend a symptom-based screening instrument, followed by PSG in patients who exceed a certain threshold, as an alternative to performing PSG in all patients. It should be noted that there is a high prevalence of obesity hypoventilation syndrome in patients who are candidates for bariatric surgery. Therefore, obesity hypoventilation syndrome should be ruled out prior to home sleep apnea testing in this population.

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.

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 is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). The MSLT and maintenance of wakefulness test 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 patients 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 or ruled out before confirming a diagnosis of narcolepsy with the MSLT. See Blue Shield of California Medical Policy: Polysomnography for Non-Respiratory Sleep Disorders.

Specialist Training
Medical professionals who interpret a polysomnogram or home sleep apnea test should be trained in sleep medicine and should review the raw data from PSG and home sleep apnea tests to detect artifacts and data loss. In addition, the treatment of patients 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 (e.g., review of symptoms and device utilization between 30 and 90 days with a minimum of 4 hours per night for at least 5 nights per week).

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

a. An AHI of at least 40 events per hour is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI between 20 and 40 events per hour, based on clinical judgment (e.g., if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP-level requirements, based on split-night studies, may be less accurate than in full-night calibrations.

b. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).

c. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM sleep, including REM sleep with the patient in the supine position.

d. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder is confirmed, but criteria b and c are not met.
Categorization of Polysomnography and Portable Monitoring

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

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

Continuous Positive Airway Pressure (CPAP)

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

Examples of failed CPAP include but are not limited to:
- Claustrophobia
- Inability to breathe through the nose
- Patient intolerance
- Discomfort or pain
- Patients requiring high pressures of CPAP (greater than 10 cm H2O) complaining of pressure discomfort

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

CPAP, OA and other device Compliance

Standard compliance guidelines require proof of using the device for a minimum of 4 hours per day at least 22 days out of a consecutive 30 day period within the preceding 90 days (in the past 3 months). For most devices, printouts of data from the devices are needed. For OAs, an attestation from the patient can be allowed.
Coding
The miscellaneous DME code E1399 is sometimes submitted as an extra charge for setup, training and instruction in the use of APAP. These services are included in payment for the device. They do not need to be addressed separately as they are covered by claims editing rules when a claim is made for payment.

Attended Studies
- **95807**: Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
- **95808**: Polysomnography; any age, 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
- **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 bilevel ventilation, attended by a technologist

Unattended Studies
- **95806**: Sleep study, unattended, simultaneous recording of heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement) (Note that this CPT code is identical to 95807 except that the study is not monitored)
- **95800**: Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time
- **95801**: Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)

95800 and 95801 differ from 95806 in the description of a single respiratory sensor (either airflow or peripheral arterial tone) instead of the standard configuration of both respiratory effort and respiratory airflow (ventilation). G0399 is similar to 95806. G0400 is best used for the new devices using 2 respiratory effort belts, oximetry and nasal pressure; however, it could also be used instead of 95801 (which does not meet criteria for approval). G0400 only states the need for at least 3 channels without specifying which ones, so review may be needed to determine which device is being requested for use.

Use of overnight oximetry alone would be indicated by the following CPT code:
- **94762**: Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)

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

Medicare created the following G codes to facilitate their national coverage decision:
- **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
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- **G0400**: Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels

The following HCPCS code is for the oral interface used with devices such as the Winx system:
- **A7047**: Oral interface used with respiratory suction pump, each

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

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

The following services are considered **inclusive** to the oral appliance: 21083, 70486, 70487, 76380, 97763, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, and 99215.

**Description**

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. 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 and oral pressure therapy.

**Related Policies**

- Actigraphy
- Home Cardiorespiratory Monitoring
- Polysomnography for Non-Respiratory Sleep Disorders
- Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

**Benefit Application**

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

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

**Regulatory Status**

A variety of oral appliances have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for 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, and The Equalizer Airway Device. FDA product code: LQZ.

In 2014, the mRNA Appliance® (BioModeling Solutions) was cleared for marketing by the FDA through the 510(k) process (K130067) for the treatment of snoring and mild-to-moderate OSA. FDA product code: LRK.

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

In 2010, a nasal expiratory resistance valve (Provent®, Ventus Medical) was cleared for marketing by the FDA through the 510(k) process for the treatment of OSA. The Winx™ system received marketing clearance in 2012. FDA product codes: OHP, OZR.

### Rationale

#### Background

**Obstructive sleep apnea**

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This causes a drop in blood oxygenation and brief arousal and can occur as frequently as every minute throughout the night. The 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.

OSA can also affect the cardiovascular and pulmonary systems. 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.

#### Diagnosis

The criterion standard for a diagnosis of sleep disorders is a polysomnogram performed in a sleep laboratory. A standard polysomnogram includes electroencephalogram (EEG), submental electromyogram, and electrooculogram (to detect rapid eye movement sleep) for sleep staging. Polysomnography also typically includes electrocardiography and monitoring of respiratory airflow, 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 polysomnography for CPAP titration.

### Table 1. Definitions of Terms and Scoring Criteria for OSA

<table>
<thead>
<tr>
<th>Terms</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>Apnea</td>
<td>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.</td>
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<tr>
<td>Hypopnea</td>
<td>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 4% arterial oxygen desaturation 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.</td>
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<tr>
<td>RERA</td>
<td>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.</td>
</tr>
<tr>
<td>AHI</td>
<td>The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep.</td>
</tr>
<tr>
<td>RDI</td>
<td>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.</td>
</tr>
<tr>
<td>REI</td>
<td>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.</td>
</tr>
<tr>
<td>OSA</td>
<td>Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep.</td>
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</tbody>
</table>
| Mild OSA   | • In adults: AHI or RDI of 5 to <15  
• In children: AHI ≥1.5 is abnormal |
| Moderate OSA | AHI or RDI of 15 to < 30  
Severe OSA | • Adults: AHI or RDI ≥30  
• Children: AHI of ≥10 |
| UARS       | Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals. |

**Positive airway pressure**

| APAP       | Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP. |
| PAP        | Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bilevel (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure. |
| PAP failure| Usually defined as an AHI >20 events per hour while using CPAP. |
| PAP intolerance | CPAP use for <4 hours per night for ≥5 nights per week; or refusal to use CPAP. CPAP intolerance may be observed in 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.

Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as two or more missed breaths, regardless of its duration in seconds. In pediatric patients, an AHI greater than 1.5 events per hour is considered abnormal, and an AHI of 10 or more may be considered severe.

A variety of devices have been developed specifically to evaluate OSA at home. They range from portable full polysomnography 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 therapy (i.e., fixed CPAP, bilevel positive airway pressure, or auto-adjusting positive airway pressure) during sleep. This evidence review, addresses CPAP, oral appliances, and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (BioModeling Solutions), Provent and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA.

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

**Literature Review**

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

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

**Suspected Obstructive Sleep Apnea**

**Clinical Context and Test Purpose**

The purpose of home sleep apnea tests in patients with suspected obstructive sleep apnea (OSA) is to diagnose the condition and to inform a decision on appropriate treatment.

The question addressed in this evidence review is: Do home sleep apnea tests improve the net health outcome?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant populations of interest are patients with suspected OSA.

**Interventions**

The tests being considered is home sleep apnea testing. Tests reviewed are multichannel home sleep testing and limited channel sleep testing (auto-adjusting positive airway pressure [APAP], Apnea Risk Evaluation System).
Comparators

The established test for OSA is in-laboratory polysomnography (PSG). Laboratory PSG is a more complex procedure than home testing and 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) (see Table 2).

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Measure</th>
<th>Description</th>
<th>Clinically Meaningful Difference (If Known)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in AHI</td>
<td>AHI</td>
<td>Mean change in AHI from baseline to posttreatment</td>
<td>Change from severe-to-moderate or mild OSA</td>
</tr>
</tbody>
</table>
| 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 |
| FOSQ | 30 questions | Disease-specific quality of life questionnaire that evaluates functional status related to excessive sleepiness | A score of ≥18 is the threshold for normal sleep-related functioning, and a change of ≥ 2 points is considered a clinically meaningful improvement |

AHI: Apnea/Hypopnea Index; ESS: Epworth Sleepiness Score; FOSQ: Functional Outcomes of Sleep Questionnaire; ODI: Oxygen Desaturation Index; OSA: obstructive sleep apnea.

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

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

Multichannel Home Sleep Apnea Testing

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. 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.

Home sleep testing with three 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. Comal 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. 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 ten 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 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 six-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 two 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 four recording channels (including oxygen saturation, respiratory movements, airflow, an electrocardiogram or heart rate), or with a device that measures peripheral arterial tone, 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
Use of Auto-Adjusting Positive Airway Pressure for Diagnosis and Treatment Supervised by a Sleep Specialist
Mulgrew et al (2007) published a randomized validation study of the diagnosis and management of OSA with a single-channel monitor followed by APAP. 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. 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 two-week trial, patients were asked to rate the perceived effect of treatment and to indicate whether they had used CPAP for more than two hours per night and were willing to continue treatment. Patients without a clear benefit of CPAP received 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. 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.

Apnea Risk Evaluation System
Ayappa et al (2008) reported on a validation study of a small apnea monitor that is self-applied to the forehead. 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.

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 positive airway pressure (PAP) therapy (191 min/d vs 105 min/d). For the telemedicine arm of this randomized trial, as reported by Fox et al (2012), the research coordinator reviewed the transmitted data daily and contacted the patient if any of the following were present: mask leak greater than 40 L/min for more than 30% of the night, less than 4 hours of use for 2 consecutive nights, machine-measured AHI of more than 10 events per hour, and 90th percentile of pressure greater than 16 cm H₂O. Evaluation by their physician sleep specialist after three months of therapy showed a similar modest decrease in AHI for the two groups (1.6 for telemedicine vs 0.7 for controls).

**Section Summary: Limited Channel Home Sleep Apnea Testing**

The evidence for limited channel home sleep apnea testing (includes type four monitors) in patients who have OSA consists of studies on diagnostic accuracy. A number of questions remain about the ability of this home sleep apnea tests to detect clinically significant OSA without sensors for respiratory effort, airflow, and oxygen saturation (or alternatively peripheral arterial tone, actigraphy, and oxygen saturation).

**Diagnosed Obstructive Sleep Apnea**

**Clinical Context and Therapy Purpose**

The purpose of medical management in patients who have OSA is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest are patients with OSA.

**Interventions**

The therapy being considered is the medical management of OSA in adults, which may include the use of various types of PAP therapy (i.e., fixed CPAP, bilevel PAP, or 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 two adjustable pressure levels. 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.

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

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.
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. The criterion standard treatment is 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 outcomes of interest are a decrease in AHI and oxygen desaturation Index on PSG and improvement in a measure of sleepiness such as the ESS or FOSQ (see Table 2), which are typically conducted within weeks or months.

Positive Airway Pressure Devices
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.10,11, Meta-analyses of 184 studies indicated that PAP use leads to clinically significant reductions in disease severity (−23 events/h; 95% CI: −29 to −18 events/h), both subjective and objective sleepiness, daytime and nighttime blood pressure, and motor vehicle accidents, and improved sleep-related 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. PAP adherence was improved with the use of educational, behavioral, troubleshooting, and telemonitoring interventions.

The review by Balk et al (2011) for AHRQ 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.4 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 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.12,13,14,15 As indicated in the AHRQ report, increased compliance with APAP devices has not been well-documented in clinical trials.16,17,18 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.19 They included 10 trials with a total of 7266 patients with sleep apnea. There were 356 major adverse cardiovascular events and 613 deaths observed during follow-up (range, 6-57 months). The analysis found no significant association of PAP with a composite outcome of acute coronary syndrome events, stroke, or vascular death (relative risk, 0.77; 95% CI, 0.53 to 1.13). Trials were grouped according to adherence to PAP (<4 vs ≥ 4 h/d), 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.20 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<0.001) 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.21 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 six to seven years after initiation of PAP. Exploratory analysis indicated that PAP might also be associated with a lower risk of cardiovascular mortality.

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.22 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<0.001). 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=0.02), but not in those diagnosed prior to surgery (relative risk, 0.75; 95% CI, 0.43 to 1.28; p=0.29); the difference between groups was statistically significant (p=0.009). 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.

Subsection Summary: PAP 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 six to seven years.

Oral Appliances
A 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.23 Meta-analysis showed that oral appliances reduced the AHI, arousal index, and Oxygen Desaturation Index, and increase oxygen saturation. However, oral appliances had no significant effect on sleep architecture or sleep efficiency. The meta-analysis found CPAP to be more effective than oral appliances in reducing the AHI, arousal index, and Oxygen Desaturation Index, and in improving oxygen desaturation, supporting the use of CPAP as first-line therapy for treating OSA.

Johal et al (2017) reported on a randomized crossover trial of ready-made vs custom-made mandibular repositioning devices.24 Twenty-five patients with mild-to-moderate OSA (mean AHI, 13.3 events per hour; range, 10.9-25 events per hour) were randomized to a 3-month trial of a ready-made or the custom-made device, with a 2-week washout between treatments. An overnight home sleep apnea test was performed at baseline and on the last night of the three-month trial period. Patients used the custom-made device for more nights per week (7 vs 3, p=0.004) and hours per night (5 vs 3, p=0.006) than the ready-made device. Treatment response...
(AHI < 5 events per hour) was obtained in 64% of patients during use of the custom-made device phase compared with a 24% response rate using the ready-made device (p < 0.001). Treatment failure (< 50% reduction in 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.

In the AHRQ report (2011) on the diagnosis and treatment of OSA in adults, the strength of the evidence that mandibular advancement devices improve sleep apnea signs and symptoms was rated moderate.3

Subsection Summary: Oral Appliances
Custom oral appliances, which may include mandibular repositioning or tongue-retaining devices, are an accepted therapy for mild-to-moderate OSA. A 2015 meta-analysis found the efficacy of oral appliances for measures of OSA but they were less effective than CPAP. The strength of evidence for mandibular repositioning devices was rated as moderate by AHRQ.

Novel OSA Treatments
Palate and Mandible Expansion
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.25 All patients had failed to comply with CPAP. Pre- and posttreatment AHI was assessed in a home sleep apnea test without the oral appliance. AHI decreased from a mean 45.9 events per hour to 16.5 (p < 0.01) after a mean 9.7 months of treatment. Singh et al (2016) and Cress (2017) reported on a series of 19 patients who had mild-to-moderate OSA who were treated with a DNA or mRNA Appliance.26 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 < 0.001) without the appliance while the Oxygen Saturation Index improved from 6.3% to 2.6% (p < 0.001). Limitations of these studies included the use of a home sleep apnea test rather than the more accurate laboratory PSG, uncertain blinding of the physician evaluating the sleep study, the small number of patients studied, the lack of intention-to-treat analysis, and the lack of long-term follow-up.

PAP-NAP
Krakow et al (2008) reported on the use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP.27 Patients had been referred by psychiatrists or primary care physicians for unspecified insomnia conditions, insomnia due to a mental disorder, or hypnogenic 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 five components: pretest instructions to maximize chances for daytime napping; introduction of PAP therapy addressing barriers to use; type 3 monitoring hookup (ten channels without electroencephalography leads); PAP therapy during one to two hours in bed in which the patient had the opportunity to fall asleep with the mask in place; and posttest 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.

Nasal Expiratory Positive Airway Pressure
Evidence on nasal EPAP includes a moderately sized RCT and a systematic review of the Provent device. Berry et al (2011) reported on an industry-sponsored multicenter, double-blind, randomized sham-controlled trial of EPAP.28 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. 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 three months, the decrease in ESS score was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1-point difference in ESS score is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of 5 or more events per hour on the device-off PSG night. The oxygenation results (Oxygenation Desaturation Index and percent of total sleep time with oxygen saturation <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduction to less than 10 events per hour (if device-off AHI was ≥10 events per hour), was greater in the EPAP group at 1 week (62% vs 27.2%) and at 3 months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and by 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing due to adverse events. Overall, the validity of these results was limited by the high dropout rate, and the clinical significance of the results is uncertain.

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

A systematic review by Riaz et al (2015) identified 18 studies (total n=920 patients) that had data on pre- and postnasal EPAP.30 Study designs included ten conference papers and eight publications (case series, cohort studies, RCTs). For patients included in the meta-analysis (n=345 patients), AHI decreased from 27.32 to 12.78 events per hour (p<0.001). For 359 patients, ESS score modestly improved from 9.9 to 7.4 (p<0.001). Data from the Berry et al (2011) RCT (described above) were not included in this meta-analysis because mean data were not reported. Response to the nasal EPAP was variable and inconsistent, and there were no clear characteristics (demographic factors, medical history, and/or physical exam finding) that predicted a favorable response.

Kureshi et al (2014) reported on a small (n=14) double-blind, pilot, crossover RCT of EPAP in children to evaluate efficacy and compliance with this new treatment.31 PSG with EPAP or a placebo device showed a significant mean improvement in Obstructive Apnea Index with EPAP (0.6 vs 4.2, p=0.01), but responses varied (three did not improve, two worsened). No other measures were statistically significant in this trial. For responders who used the devices at home for 30 days, adherence was 83% of nights. ESS scores improved from 11 to 7 (p=0.031) and Obstructive Sleep Apnea-18 questionnaire scores improved from 50 to 39 (p=0.028). Other outcome measures did not improve significantly.
Oral Pressure Therapy

No full-length, peer-reviewed studies on oral pressure therapy were identified in the published literature. Therefore, it is not possible to evaluate the efficacy of this treatment based on scientific evidence.

Section Summary: Novel OSA Treatments

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

The evidence on EPAP devices in patients with OSA has been reported in several prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in AHI with a minor impact on oxygenation and ESS scores.

One comparative trial with historical controls used a PAP-NAP study of patients with complex insomnia who are resistant to CPAP titration or use. This single study of PAP-NAP does not provide sufficient evidence to form conclusions on the efficacy of this approach in improving compliance with CPAP. The patient population 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.

There is no evidence on the use of oral pressure therapy to treat OSA.

Summary of Evidence

Diagnosis

For individuals who have suspected OSA who receive home sleep apnea testing with at least three recording channels, the evidence includes RCTs. The relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. RCTs have reported that home sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone, actigraphy and oxygen saturation) is noninferior to testing in the sleep lab for adults with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation. A positive portable monitoring study with channels that include arterial oxygen saturation, airflow, and respiratory effort has a high positive predictive value for OSA and can be used as the basis for a CPAP trial to determine the efficacy of treatment. A negative portable monitoring study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or have a positive study but do not respond to CPAP should undergo further evaluation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have suspected OSA who receive limited channel home sleep apnea testing, the evidence includes studies on diagnostic accuracy. The relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. The ability to detect clinically significant OSA without sensors for respiratory effort, airflow, and oxygen saturation, or alternatively without peripheral arterial tone, actigraphy and oxygen saturation, lacks support in the literature. The evidence is insufficient to determine the effects of the technology on health outcomes.

Treatment

For individuals who have OSA who receive PAP devices or oral appliances, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, functional outcomes, and QOL. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. A diagnostic sleep study may be followed by a trial of APAP to evaluate the efficacy and adjust pressure. APAP or bilevel PAP may also be indicated if the patient is intolerant of CPAP. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
For individuals who have OSA who receive novel OSA treatments (e.g., palate expansion, EPAP, oral pressure therapy), the evidence includes an RCT and a meta-analysis of case series. The relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on EPAP devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the AHI, with minor impact on oxygenation, and a decrease in ESS score. One comparative trial with historical controls used a PAP-NAP to study patients with complex insomnia resistant to CPAP titration or use. Additional study is needed to evaluate with greater certainty the efficacy of this intervention. No evidence was identified on the use of the oral therapy device. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
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 from Blue Cross Blue Shield Association, input was received from 7 physician specialty societies (8 reviewers) and 4 academic medical centers (6 reviewers) 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 obstrucive sleep apnea (OSA) in patients with a body mass index greater than 40 kg/m², 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 from Blue Cross Blue Shield Association, input was received from 1 physician specialty society and 6 academic medical centers (8 reviewers) 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 four 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 from Blue Cross Blue Shield Association, input was received from 5 physician specialty societies (6 reviewers) and 3 academic medical centers in 2009. Professional society guidelines and position statements were also reviewed. In general, input supported the use of polysomnography, portable sleep monitoring tests, multiple sleep latency tests, and continuous positive airway pressure 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
American Academy of Sleep Medicine
The AASM (2017) published clinical practice guidelines on diagnostic testing for adult OSA. The AASM provided the following recommendations (see Table 3).
Table 3. Recommendations on Diagnostic Testing for Adult OSA

<table>
<thead>
<tr>
<th>Recommendation Statement</th>
<th>SOR</th>
<th>QOE</th>
<th>Benefits vs Harms</th>
</tr>
</thead>
<tbody>
<tr>
<td>We recommend that clinical tools, questionnaires, and prediction algorithms not be used to diagnose OSA in adults, in the absence of PSG or HSAT.</td>
<td>Strong</td>
<td>Moderate</td>
<td>High certainty that harms outweigh benefits</td>
</tr>
<tr>
<td>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.</td>
<td>Strong</td>
<td>Moderate</td>
<td>High certainty that benefits outweigh harms</td>
</tr>
<tr>
<td>We recommend that if a single HSAT is negative, inconclusive, or technically inadequate, PSG be performed for the diagnosis of OSA.</td>
<td>Strong</td>
<td>Low</td>
<td>High certainty that benefits outweigh harms</td>
</tr>
<tr>
<td>We recommend that if a single HSAT is negative, inconclusive, or technically inadequate, PSG be performed for the diagnosis of OSA.</td>
<td>Strong</td>
<td>Low</td>
<td>High certainty that benefits outweigh harms</td>
</tr>
<tr>
<td>We recommend that PSG, rather than home sleep testing, be used for patients with significant cardiopulmonary disorder, potential respiratory muscle weakness, awake or suspected sleep hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.</td>
<td>Strong</td>
<td>Very low</td>
<td>High certainty that benefits outweigh harms</td>
</tr>
<tr>
<td>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.</td>
<td>Weak</td>
<td>Low</td>
<td>Low certainty that benefits outweigh harms</td>
</tr>
<tr>
<td>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.</td>
<td>Weak</td>
<td>Very low</td>
<td>Low certainty that benefits outweigh harms</td>
</tr>
</tbody>
</table>

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

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.

The AASM also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA. 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).

**Diagnosis**

The AASM recommended that patients who are obese, retrognathic, hypertensive, or who complain of snoring or daytime sleepiness should be assessed for presence or absence as well as the severity of OSA using the following methods (standard):

- Sleep history assessment includes witnessed apneas, gasping/choking at night, excessive sleepiness, total sleep amount, nocturia, morning headaches, and decreased concentration and memory.
- Physical assessment includes evaluation of respiratory, cardiovascular, and neurologic systems and signs of upper respiratory narrowing.
- Objective testing, under an AASM-accredited program, and attended by trained technical personnel. The diagnosis of OSA is confirmed if the number of obstructive events (apneas, hypopneas plus respiratory event related to arousals) is greater than 15 events/hour or greater than 5 events/hour in a patient reporting any of the following: unintentional sleep episodes during wakefulness; daytime sleepiness; unrefreshing sleep; fatigue; insomnia; waking up breath holding, gasping, or choking; and a bed partner describing loud snoring, breathing interruptions, or both.
  - In laboratory polysomnography (standard) records electroencephalogram, electrooculogram, chin electromyogram, airflow, oxygen saturation, respiratory effort, and heart rate.
Home testing with portable monitors should at minimum, record airflow, respiratory effort, and blood oxygenation.

Treatment with positive airway pressure

- Continuous positive airway pressure (CPAP) is indicated for patients with moderate to severe OSA (Standard) and mild OSA (Option).
- Bilevel positive airway pressure can be considered in CPAP-intolerant patients (Consensus).
- Auto titrating positive airway pressure 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) published a clinical practice guideline on the treatment of OSA with positive airway pressure (PAP) that was based on a systematic review of the evidence. 

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
- Use of PAP to treat OSA in adults with comorbid hypertension
- Use CPAP or APAP over BPAP in the routine treatment of OSA
- That behavioral and/or troubleshooting interventions be given during the initial period of PAP therapy
- That clinicians use telemonitoring during the initial period of PAP therapy

The AASM and the American Academy of Dental Sleep Medicine (2015) published guidelines on the treatment of OSA and snoring with oral appliance therapy. The two societies provided a recommendation of “standard” that sleep physicians consider prescription of oral appliance, 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.

The AASM (2011) published evidence-based guidelines on respiratory indications for PSG in children. "Standard" recommendations were made for the following: PSG in children should be performed and interpreted in accordance with the AASM Manual for the Scoring of Sleep and Associated Events; PSG is indicated when the clinical assessment suggested the diagnosis of OSA in children; children with mild OSA preoperatively should have clinical evaluation following adenotonsillectomy to assess for residual symptoms. If there are residual symptoms of OSA, PSG...
should be performed; PSG was indicated following adenotonsillectomy to assess for residual OSA in children with preoperative evidence for moderate-to-severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, and neurologic disorders; PSG was indicated for positive airway pressure titration in children with OSA.

The AASM (2017) published a position statement on the clinical use of a home sleep apnea test. The AASM indicated that a home sleep apnea test should be ordered by a physician after “face-to-face examination” to diagnose OSA or evaluate treatment efficacy and should not be used for general screening of asymptomatic populations. The AASM supported the review of raw data and interpretation by a physician board-certified in sleep medicine, stating that automatically scored data “could lead to sub-optimal care that jeopardizes patient health and safety”.

**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. 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 College of Physicians**
The guidelines on the diagnosis of OSA in adults from the American College of Physicians (ACP; 2014) recommended that clinicians target their assessment of OSA to individuals with unexplained daytime sleepiness. The ACP recommended PSG for diagnostic testing in patients suspected of OSA, and portable sleep monitors in patients without serious comorbidities as an alternative to PSG when PSG is not available for diagnostic testing (weak recommendation, moderate-quality evidence). Inconclusive areas of evidence included preoperative screening for OSA, phased testing for the diagnosis of OSA, and the utility of portable monitors for diagnosis OSA in patients with comorbid conditions.

The ACP (2013) guidelines on the management of OSA in adults recommended that all overweight and obese patients diagnosed with OSA be encouraged to lose weight (strong recommendation, low-quality evidence). The ACP recommended CPAP as initial therapy for patients diagnosed with OSA (strong recommendation; moderate-quality evidence), and mandibular advancement devices as an alternative therapy to CPAP for patients diagnosed with OSA who prefer mandibular advancement devices or for those with adverse events associated with CPAP (weak recommendation, low-quality evidence).

**American Academy of Craniofacial Pain**
The American Academy of Craniofacial Pain (2013) published a position paper. It indicated that oral appliance therapy was recognized as an effective therapy for many with primary snoring and mild-to-moderate OSA, as well as those with more severe OSA who cannot tolerate PAP therapies, but that oral appliance therapy has the potential to cause adverse events, including temporomandibular joint pain and dysfunction. The Academy recommended that dentists engaged in, or who want to engage in, the assessment and management of patients with snoring and OSA using mandibular advancement OA be properly trained and experienced.
in the assessment, diagnosis, and management of temporomandibular joint and craniofacial pain.

**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). 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.**
2. **[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.**
3. **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.**
4. **No clear guidelines exist upon which to base recommendations for retesting for OSA following bariatric surgery.**

**American Academy of Otolaryngology-Head and Neck Surgery**
The American Academy of Otolaryngology-Head and Neck Surgery (2011) published guidelines on PSG for sleep-disordered breathing prior to tonsillectomy in children, which included the following:

1. **Before determining the need for tonsillectomy, the clinician should refer children with SDB [sleep-disordered breathing] for PSG if they exhibit the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses.**
2. **The clinician should advocate for PSG prior to tonsillectomy for SDB in children without any of the comorbidities [listed above] for whom the need for surgery is uncertain or when there is discordance between tonsillar size of physical examination and the reported severity of SDB.**
3. **Clinicians should communicate PSG results to the anesthesiologist prior to the induction of anesthesia for tonsillectomy in a child with SDB.**
4. **Clinicians should admit children with OSA documented on PSG for inpatient, overnight monitoring after tonsillectomy if they are younger than age 3 years or have severe OSA (apnea-hypopnea index of 10 or more obstructive events/hour, oxygen saturation nadir less than 80%, or both).**
5. **In children for whom PSG is indicated to assess SDB prior to tonsillectomy, clinicians should obtain laboratory-based PSG, when available.**

**American Thoracic Society**

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

**U.S. Preventive Services Task Force Recommendations**
The U.S. Preventive Services Task Force (2017) reported on the evidence assessing screening for OSA in adults and concluded that “the current evidence is insufficient to assess the balance and harms of screening for obstructive sleep apnea (OSA) in asymptomatic adults. Evidence on
screening tools to accurately detect persons in asymptomatic populations who should receive further testing and treatment of subsequently diagnosed OSA to improve health outcomes is lacking, and the balance of benefits and harms cannot be determined.44,45.

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

The CMS (2008) expanded coverage of CPAP to include those beneficiaries with a diagnosis of OSA made with a combination of clinical evaluation and unattended home sleep monitoring using a device with at least 3 channels.46,47. There is variability in the published medical literature about the definition of the events that constitute a respiratory disturbance, and, for the purposes of this national coverage decision, a respiratory disturbance was defined in the context of the sleep test technology of interest and, for portable monitoring devices that do not measure AHI or Respiratory Disturbance Index (RDI) directly, does not require direct measurement of airflow.

Effective in March 2008, CMS determined that CPAP therapy, when used in adults with OSA, would be considered reasonable and necessary in the following situations:
1. The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.
2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example, a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.
3. A positive diagnosis of OSA for the coverage of CPAP must include clinical evaluation and a positive:
   a. attended PSG performed in a sleep laboratory; or
   b. unattended HST [home sleep test] with a Type II home sleep monitoring device; or
   c. unattended HST with a Type III home sleep monitoring device; or
   d. unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels
4. The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision.
5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criteria using the AHI or RDI are met:
   a. AHI or RDI greater than or equal to 15 events per hour, or
   b. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke
6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at minimum the number of events that would have been required in a 2-hour period.
7. Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in
8. Coverage with Evidence Development (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions:
   a. In Medicare aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Types II, III & IV HST in identifying subjects with OSA who will respond to CPAP?
   b. In Medicare aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Types II, III & IV HST, does CPAP cause clinically meaningful harm?

In March 2009, CMS issued a national coverage decision (CAG-00405N) for the types of sleep testing devices that would be approved for coverage. CMS found that the evidence was sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA:

1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. A Type II or Type III sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
3. A type IV sleep testing device measuring three or more channels, one of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
4. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in May 2019 identified over 200 studies on diagnosis and medical management of OSA.

References


**Documentation for Clinical Review**

**Please provide the following documentation (if/when requested):**

- History and physical and/or consultation notes including:
  - Documentation of obstructive sleep apnea including:
    - AHI/RDI/REI
    - Symptoms
    - Comorbidities
  - Type of sleep study that is being requested
  - Reason for requested study
  - Current treatment plan
  - Prior treatment and response (including documented failed trial of CPAP; if applicable)
  - Completed sleep questionnaires (e.g., Epworth Sleepiness Scale, Berlin Questionnaire, STOP-Bang)
  - Prior Polysomnography or Sleep study reports; if applicable
  - Sleep specialist physician recommendation and prescription for positive airway pressure device or intraoral appliance; if applicable

**Post Service**

- Polysomnography or Home Sleep study reports
- Operative report(s); if applicable

**Coding**
This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**MN/IE**
The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>21083</td>
<td>Impression and custom preparation; palatal lift prosthesis</td>
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<tr>
<td></td>
<td>21089</td>
<td>Unlisted maxillofacial prosthetic procedure</td>
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<tr>
<td></td>
<td>21110</td>
<td>Application of interdental fixation device for conditions other than fracture or dislocation, includes removal</td>
</tr>
<tr>
<td></td>
<td>21299</td>
<td>Unlisted craniofacial and maxillofacial procedure</td>
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<td></td>
<td>70486</td>
<td>Computed tomography, maxillofacial area; without contrast material</td>
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<td>70487</td>
<td>Computed tomography, maxillofacial area; with contrast material(s)</td>
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<td>76380</td>
<td>Computed tomography, limited or localized follow-up study</td>
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<td>94660</td>
<td>Continuous positive airway pressure ventilation (CPAP), initiation and management</td>
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<td></td>
<td>94762</td>
<td>Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)</td>
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<td>Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist</td>
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<tr>
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<td>95783</td>
<td>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</td>
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<td>Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time</td>
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<td>95801</td>
<td>Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)</td>
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<td></td>
<td>95805</td>
<td>Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness</td>
</tr>
<tr>
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<td>95806</td>
<td>Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)</td>
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<td>95807</td>
<td>Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist</td>
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<td>95808</td>
<td>Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist</td>
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<td>95810</td>
<td>Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist</td>
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<tr>
<td></td>
<td>95811</td>
<td>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</td>
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</table>
### Type | Code | Description
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| | 97763 | Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
| 99201 | Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family.
| 99202 | Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.
| 99203 | Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.
| 99204 | Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.
| 99205 | Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.
| 99211 | Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.
### Type | Code | Description
--- | --- | ---
Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family. | 99212 | 
Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family. | 99213 | 
Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family. | 99214 | 
Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family. | 99215 | 
Combination oral/nasal mask, used with continuous positive airway pressure device, each | A7027 | 
Oral cushion for combination oral/nasal mask, replacement only, each | A7028 | 
Nasal pillows for combination oral/nasal mask, replacement only, pair | A7029 | 
Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap | A7034 | 
Headgear used with positive airway pressure device | A7035 | 
Chinstrap used with positive airway pressure device | A7036 | 
Tubing used with positive airway pressure device | A7037 | 
Filter, disposable, used with positive airway pressure device | A7038 | 
Filter, nondisposable, used with positive airway pressure device | A7039 | 
Oral interface used with respiratory suction pump, each | A7047 |
<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>E0470</td>
<td>Respiratory assist device, bi-level pressure capability, without back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)</td>
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<tr>
<td></td>
<td>E0471</td>
<td>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)</td>
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<tr>
<td></td>
<td>E0485</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment</td>
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<tr>
<td></td>
<td>E0486</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment</td>
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<tr>
<td></td>
<td>E0561</td>
<td>Humidifier, nonheated, used with positive airway pressure device</td>
</tr>
<tr>
<td></td>
<td>E0562</td>
<td>Humidifier, heated, used with positive airway pressure device</td>
</tr>
<tr>
<td></td>
<td>E0601</td>
<td>Continuous positive airway pressure (CPAP) device</td>
</tr>
<tr>
<td></td>
<td>G0398</td>
<td>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</td>
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<tr>
<td></td>
<td>G0399</td>
<td>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</td>
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<tr>
<td></td>
<td>G0400</td>
<td>Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels</td>
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<tr>
<th>ICD-10 Procedure</th>
<th>Description</th>
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<tr>
<td>4A1ZXQZ</td>
<td>Monitoring of Sleep, External Approach</td>
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<tr>
<td>5A09357</td>
<td>Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours, Continuous Positive Airway Pressure</td>
</tr>
<tr>
<td>5A09358</td>
<td>Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours, Intermittent Positive Airway Pressure</td>
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<tr>
<td>5A0935Z</td>
<td>Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours</td>
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<tr>
<td>5A09457</td>
<td>Assistance with Respiratory Ventilation, 24-96 Consecutive Hours, Continuous Positive Airway Pressure</td>
</tr>
<tr>
<td>5A09458</td>
<td>Assistance with Respiratory Ventilation, 24-96 Consecutive Hours, Intermittent Positive Airway Pressure</td>
</tr>
<tr>
<td>5A0945Z</td>
<td>Assistance with Respiratory Ventilation, 24-96 Consecutive Hours</td>
</tr>
<tr>
<td>5A09557</td>
<td>Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours, Continuous Positive Airway Pressure</td>
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<tr>
<td>5A09558</td>
<td>Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours, Intermittent Positive Airway Pressure</td>
</tr>
<tr>
<td>5A0955Z</td>
<td>Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours</td>
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</tbody>
</table>

**Policy History**

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

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
<td>04/03/2009</td>
<td>Policy title change</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Policy revision with position change</td>
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<tr>
<td></td>
<td>Policy combined:</td>
<td>Medical Policy Committee</td>
</tr>
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</table>
## Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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

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

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

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

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