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| 2.01.18 | Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome | | |
| Original Policy Date: | April 3, 2009 | Effective Date: | July 1, 2022 |
| Section: | 2.0 Medicine | Page: | Page 1 of 51 |

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](#) obstructive sleep apnea (OSA) in adults unless contraindicated.

Prior authorization is not required for HSATs. However, treatment based on HSAT results will not be approved unless the following criteria are met:

- I. Documentation that the device used meets the following criteria:
 - A. A minimum of 3 recording channels with **all** of the following sensors:
 1. Nasal pressure
 2. Chest and abdominal respiratory inductance plethysmography
 3. Oximetry; OR
 - B. Utilization of Peripheral Arterial Tone (PAT) with oximetry and actigraphy
 - C. The patient is at least 18 years old
 - D. There are no contraindications to a home sleep study

Supervised Polysomnography (PSG) in a Sleep Laboratory

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 when appropriate unless documentation is provided why it cannot or was not done.

- I. An initial supervised polysomnography (PSG) performed in a [sleep laboratory](#) may be considered **medically necessary** for a patient with a moderate or high pretest probability of OSA in **any** of the following situations:
 - A. A previous home study failed to establish the diagnosis of OSA in a patient with a high pretest probability of OSA
 - B. A previous home study was technically inadequate
 - C. Failure of resolution of symptoms or recurrence of symptoms during treatment
 - D. Presence of a known comorbidity (a contraindication to HSAT) that might alter ventilation or decrease the accuracy of a home sleep apnea test, including, but not limited to significant, ongoing symptoms 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 arrhythmias
 - E. 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)
 - F. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA
 - G. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed
 - H. Pediatric patient (i.e., less than 18 years of age)
- II. A repeated, supervised polysomnography (PSG) performed in a [sleep laboratory](#) may be considered **medically necessary** for a patient with a moderate or high pretest probability of OSA in **any** of the following situations:

- A. To initiate and titrate CPAP for an adult patient who has [clinically significant OSA](#)
 - B. Failure of resolution of symptoms or recurrence of symptoms during treatment
 - C. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA
 - D. 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)
 - E. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed
 - F. To assess efficacy of adenotonsillectomy for a patient under the age of 18
 - G. To initiate and titrate CPAP for a child with **either** of the following:
 - 1. An AHI or RDI of greater than or equal to 5 events per hour
 - 2. 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
- III. Auto-adjusting positive airway pressure (APAP) may be considered **medically necessary** for the titration of pressure as an alternative to a CPAP titration PSG or CPAP use in adults with [clinically significant OSA](#).

Medical Management

- IV. [CPAP](#) (or APAP) 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](#) diagnostic study.
- V. Bilevel positive airway pressure (BiPAP) may be considered **medically necessary** with **both** of the following:
 - A. Patient has [clinically significant OSA](#)
 - B. Patient failed a prior trial of CPAP or whom BiPAP is found to be more effective in the [sleep lab](#)
- VI. [Replacement of a PAP device](#) after the warranty period (usually 2-5 years) may be considered **medically necessary** with **all** of the following:
 - A. Documentation that the device is no longer functioning properly
 - B. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
 - C. Documentation of current compliance prior to the problem with the machine
 - D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)
 - E. Documentation the device is out of warranty
- VII. [Replacement of a PAP device](#) within the warranty period may be considered **medically necessary** with **all** of the following:
 - A. Documentation that the device is no longer functioning properly
 - B. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
 - C. Documentation of current compliance prior to the problem with the machine
 - D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)
 - E. Documentation that the cost of repairs would exceed that of replacement
- VIII. A single oral appliance (tongue-retaining devices or mandibular advancing/positioning devices) may be considered **medically necessary** in adults with [clinically significant OSA](#) when **all** of the following conditions have been met:
 - A. Initial or continued use of CPAP is [clinically not tolerated or is refused by the patient](#)
 - B. The device is prescribed by a treating physician
 - C. The device is custom-fitted by qualified dental personnel

- D. There is documentation of absence of temporomandibular dysfunction or periodontal disease
 - E. Physician has reviewed, completed and signed an [OSA Oral Appliance Therapy Check-off List](#) (signed copy attached to request in addition to appropriate medical record documentation supporting the check list)
- IX. [Replacement of an oral appliance](#) (OA) *after* the warranty period (usually 3 years) may be considered **medically necessary** with **all** of the following:
- A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate
 - B. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
 - C. Documentation of current compliance prior to the problem with the OA
 - D. Documentation of benefit from the use of the OA (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)
 - E. Physician has reviewed, completed and signed an [OSA Oral Appliance Therapy Check-off List](#) (signed copy attached to request)
- X. [Replacement of an oral appliance](#) (OA) *within* the warranty period may be considered **medically necessary** with **all** of the following:
- A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate
 - B. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
 - C. Documentation of current compliance prior to the problem with the OA
 - D. Documentation of benefit from the use of the OA
 - E. Documentation that the cost of repairs would exceed that of replacement
 - F. Physician has reviewed, completed and signed an [OSA Oral Appliance Therapy Check-off List](#) (signed copy attached to request)
- XI. [Replacement of an oral appliance](#) due to changes in dental alignment may be considered **medically necessary** with **all** of the following:
- A. Documentation of [clinically significant OSA](#) (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)
 - B. Physician has reviewed, completed and signed an [OSA Oral Appliance Therapy Check-off List](#) (signed copy attached to request)
 - C. Initial or continued use of CPAP is not tolerated or is refused by the patient
 - D. The device is prescribed by a treating physician
 - E. The device is custom fitted by qualified dental personnel
 - F. There is documentation of absence of significant temporomandibular dysfunction and periodontal disease
 - G. Needed after completion of orthodontic treatment that was prescribed and supervised by an orthodontist
- XII. The following are considered **investigational**:
- A. Nasal expiratory positive airway pressure
 - B. Oral pressure therapy devices
 - C. Mandibular/palatal expansion devices for the treatment of OSA
 - D. The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP)
 - E. The use of a sleep positioning trainer with vibration
 - F. The use of daytime electrical stimulation of the tongue
 - G. The use of CPAP, bi-level positive airway pressure, APAP, ASV and intraoral appliances that do not meet the above criteria for the treatment of OSA
 - H. Unattended home sleep apnea test for a child (younger than 18 years of age)
 - I. Multiple sleep latency testing (MSLT) in the initial workup (diagnosis) of OSA

- J. Mandibular repositioning (daytime), bruxism and anti-snoring oral appliances for the treatment of OSA

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

Policy Guidelines

Home Sleep Apnea Test Devices

American Academy of Sleep Medicine (AASM) updated their guidelines in 2019 to recommend devices using BOTH a respiratory and abdominal belt (dual belt). Heart rate is no longer required. In addition, devices using PAT technology (e.g., WatchPAT) are also recommended. Since many existing devices (such as many 4 channel devices) will not meet these criteria, the previous standard 4 channel tests (CPT 95806) will no longer be accepted as support for needing treatment after the period of transition that has previously been provided. The WatchPAT device uses CPT code 95800, and is now allowed as an acceptable device choice.

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

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

A home sleep apnea test should include one of the following:

- A minimum of 3 recording channels with the following sensors:
 - Nasal pressure
 - Chest and abdominal respiratory inductance plethysmography
 - Oximetry
- Peripheral Arterial Tone (PAT) with oximetry and actigraphy

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 acceptable of an initial sleep apnea diagnostic test.

Contraindications to HSAT

Contraindications to home sleep studies include, but are not limited to significant, ongoing symptoms related to:

- Central sleep apnea
- Symptomatic heart failure
- Symptomatic chronic pulmonary disease
- Obesity hypoventilation syndrome
- Neuromuscular disorders with sleep-related symptoms
- Stroke or recurrent Transient Ischemic Attacks (TIAs)
- Coronary Artery Disease
- Tachycardic or bradycardic arrhythmias
- Injurious or potentially injurious parasomnias
- Narcolepsy

Sleep Lab Test

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

Definition of Obstructive Sleep Apnea

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

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

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

Clinically Significant OSA in an adult

Includes either of the following:

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

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

Hypertension

Systolic BP ≥ 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_{CO2} >45 mm Hg or serum bicarbonate ≥ 27) among patients with body mass index ≥ 30 kg/m² 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 (**S**nore, **T**ired, **O**bserved apnea, blood **P**ressure, **B**MI, **A**ge, **N**eck, **G**ender) 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.

Specialist Training

Polysomnography (PSG) or home sleep apnea testing should be performed in appropriately selected patients and the test summary results reviewed by a physician who is trained in sleep medicine. 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:

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

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

Categorization of Polysomnography and Portable Monitoring

Full correspondence does not exist between CPT codes and the most current categorization scheme for the different types of studies. The 2005 practice parameters from the American Academy of Sleep Medicine list 4 types of monitoring procedures: type 1, standard attended in-lab comprehensive PSG; type 2, comprehensive portable PSG; type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of 4 or more channels of monitoring; and type 4, continuous single or dual bioparameters, consisting of 1 or 2 channels, typically oxygen saturation, or airflow. Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and PSG are often used interchangeably. CPT coding distinguishes

between sleep studies that do not include electroencephalographic (EEG) monitoring, and PSG, which includes EEG monitoring. PSG is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the patient's home. There are no specific codes for remotely monitored home sleep studies. They would likely be reported with the CPT code for the sleep study with the GT modifier ("via interactive audio and video telecommunications systems") appended. There is no CPT code for "unattended" PSG.

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

Continuous Positive Airway Pressure (CPAP)

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

Examples of failed CPAP include but are not limited to:

- Claustrophobia
- Inability to breathe through the nose
- Patient intolerance
- Discomfort or pain
- Patients requiring high pressures of CPAP (greater than 10 cm 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.

Compliance

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

CPAP and Oral Appliance

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

Replacement of a PAP device

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

Coding

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

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

- **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)
- **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 and 95801 differ from 95806 in the description of a single respiratory sensor (either air flow or peripheral arterial tone) instead of the 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
- **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

Effective April 1, 2022, the following HCPCS codes may be used for tongue neuromuscular stimulation device:

- **K1028:** Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
- **K1029:** Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply

The following new HCPCS code represents Respiroics products such as the Lunoa System which has 3 components operated as one system to provide positional obstructive sleep apnea treatment:

- **K1001:** Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type

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

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

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

Description

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. Polysomnography and portable sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone (PAT), actigraphy, and oxygen saturation are established methods for diagnosing OSA. Other proposed methods of diagnosing OSA include limited channel home sleep monitors. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous positive airway pressure (CPAP) during sleep. Novel treatments include nasal expiratory positive airway pressure (EPAP) and oral pressure therapy.

Related Policies

- Actigraphy
- 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 Smartfusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, DeSRA, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device. FDA product code: LQZ.

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

Novel devices for OSA diagnosis and treatment are described in Table 1.

Table 1. Novel Devices for OSA Diagnosis and Treatment

| Device | Manufacturer | Description | FDA Marketing Clearance | FDA Product Code | Year |
|---------------------------|--------------------------------|--|-------------------------|------------------|------|
| Diagnosis | | | | | |
| SleepImage System | MyCardio | Software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor to aid in the evaluation of sleep disorders. | K163696 | MNR | 2017 |
| Treatment | | | | | |
| Provent® | Ventus Medical | Nasal expiratory resistance valve. | | OHP | 2010 |
| Winx™ | | Nasal expiratory resistance valve. | | OZR | 2012 |
| mRNA Appliance® | BioModeling Solutions | Expandable oral appliance for the treatment of snoring and mild-to-moderate OSA | K130067 | LRK | 2014 |
| NightBalance Lunoa System | Philips | The positional sleep trainer is worn with an elasticized chest strap, and is intended to keep patients with positional obstructive sleep apnea from sleeping in the supine position. | K180608 | MYB | 2018 |
| eXciteOSA® | Signifier Medical Technologies | The device delivers neuromuscular stimulation during the day to strengthen the tongue in order to reduce snoring and mild sleep apnea. It is used for 20 minutes once a day for a period of 6-weeks, and once a week thereafter. | DEN200018 | QNO | 2021 |

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

Rationale

Background

Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This causes a drop in blood oxygenation and brief arousal and can occur as frequently as every minute throughout the night. The 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.¹ For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This, in turn, can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile collisions related to daytime sleepiness. It is estimated that about 7% of adults have moderate or severe OSA, 20% have mild OSA, and the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease.¹

Diagnosis

The criterion standard for a diagnosis of sleep disorders is a polysomnogram performed in a sleep laboratory.² A standard polysomnogram includes electroencephalogram (EEG), submental electromyogram, and electrooculogram (to detect rapid eye movement sleep) for sleep staging. Polysomnography 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 2. Definitions of Terms and Scoring Criteria for OSA

| Terms | Definition |
|-------------------|--|
| Respiratory event | |
| Apnea | The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds. |
| Hypopnea | Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 3% or 4% arterial oxygen desaturation (depending on criteria) or an arousal. Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or associated arousal. |

| Terms | Definition |
|-----------------------------|---|
| RERA | Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea |
| Respiratory event reporting | |
| AHI | The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep |
| RDI | The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI. |
| REI | The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available. |
| OSA | Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep |
| Mild OSA | In adults: AHI or RDI of 5 to <15. In children: AHI \geq 1.0 to <5 |
| Moderate OSA | AHI or RDI of 15 to <30; Children: AHI of \geq 5 to <10 |
| Severe OSA | Adults: AHI or RDI \geq 30; Children: AHI of \geq 10 |
| UARS | Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals. |
| Positive airway pressure | |
| APAP | Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP |
| PAP | Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure. |
| PAP failure | Usually defined as an AHI >20 events per hour while using CPAP |
| PAP intolerance | CPAP use for <4 hours per night for \geq 5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in 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 2 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 Apnea/hypopnea Index (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, Phyll 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 established and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (BioModeling Solutions), eXciteOSA (Signifier Medical Technologies), NightBalance Sleep Position Trainer (Phillips), Provent and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA.

Surgical management of OSA (i.e., adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in evidence review 7.01.101 (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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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 in patients with suspected OSA?

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

Populations

The relevant population of interest is patients with suspected OSA.

Interventions

The test 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 3).

Table 3. Health Outcome Measures Relevant to OSA

| Outcome | Measure | Description | Clinically Meaningful Difference (If Known) |
|---------------|---------|---|---|
| Change in AHI | AHI | Mean change in AHI from baseline to posttreatment | Change from severe-to-moderate or mild OSA |

| Outcome | Measure | Description | Clinically Meaningful Difference (If Known) |
|-------------|--|---|---|
| AHI success | Percentage of patients achieving success | Studies may use different definitions of success, but the most common for AHI success is the Sher criteria | Sher criteria include a decrease in AHI of $\geq 50\%$ and an AHI < 20 events per hour. Alternative measures of success may be AHI < 15 , < 10 , or < 5 events per hour |
| ODI | Oxygen levels in blood during sleep | The number of times per hour of sleep that the blood oxygen level drops by ≥ 4 percentage points | More than 5 events per hour |
| ESS | Scale ranges from 0 to 24 | The ESS is a short self-administered questionnaire that asks patients how likely they are to fall asleep in 8 different situations (e.g., watching TV, sitting quietly in a car, or sitting and talking to someone) | An ESS of ≥ 10 is considered excessively sleepy. A decrease of 2 points is considered the MID. ³ |
| FOSQ | 30 questions | Disease-specific quality of life questionnaire that evaluates functional status related to excessive sleepiness | A score of ≥ 18 is the threshold for normal sleep-related functioning, and a change of ≥ 2 points is considered a clinically meaningful improvement |

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

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

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

Study Selection Criteria

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

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

Review of Evidence

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

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

Subsection Summary: Multichannel Home Sleep Apnea Testing

Based on this evidence and society guidelines, portable monitoring with a minimum of 4 recording channels (including oxygen saturation, respiratory movements, airflow, an electrocardiogram or heart rate), or with a device that measures peripheral arterial tone, 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.⁶ They developed a diagnostic algorithm that had a 94% positive predictive value for moderate-to-severe OSA assessed by PSG. Patients who passed the screening (n=68) were randomized to attend in-laboratory PSG with CPAP titration or home monitoring with a portable APAP unit. No difference was observed between lab PSG and home-managed patients for any of the outcome measures. Senn et al (2006) assessed whether an empirical approach, using a 2-week trial of APAP, could effectively diagnose OSA.⁷ Patients (N=76) were included in the study if they had been referred by primary care physicians for evaluation of suspected OSA, were habitual snorers, complained of daytime sleepiness, and had an ESS score of 8 or greater (mean, 13.6). At the end of the 2-week trial, patients were asked to rate the perceived effect of treatment and to indicate whether they had used CPAP for more than 2 hours per night and were willing to continue treatment. Patients without a clear benefit of CPAP received further evaluation, including clinical assessment and PSG. Compared with PSG, patient responses showed a sensitivity of 80%, a specificity of 97%, a positive predictive value of 97%, and a negative predictive value of 78%.

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

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

SleepImage System

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

Table 4. Clinical Validity of the SleepImage System

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

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

Subsection Summary: Limited Channel Home Sleep Apnea Testing

The evidence for limited channel home sleep apnea testing (includes type 4 monitors) in patients who have OSA consists of studies on diagnostic accuracy. A number of questions remain about the ability of these home sleep apnea tests to detect clinically significant OSA without sensors for respiratory effort, airflow, and oxygen saturation (or alternatively 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 positive airway pressure (PAP), oral appliances, or novel OSA treatments improve the net health outcome in patients who have OSA?

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

Populations

The relevant population of interest is 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 2 adjustable pressure levels for inspiration and expiration. APAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been hypothesized

that both bilevel PAP and APAP are more comfortable for the patient and thus might improve patient compliance or acceptance.

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.

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

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

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

Comparators

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

Outcomes

The 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 3), which are typically conducted within weeks or months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

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.^{11,12} 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.^{13,14,15,16} As indicated in the AHRQ report, increased compliance with APAP devices has not been well-documented in clinical trials.^{17,18,19} 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.²⁰ 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.²¹ With a mean duration of adherence to CPAP therapy of 3.3 hours per night, CPAP significantly reduced daytime sleepiness (adjusted difference in ESS score, -2.5; 95% CI, -2.8 to -2.2; p<.001) and improved health-related QOL and mood. Lisan et al (2019) reported 11-year follow-up of a cohort of 392 patients from the Sleep Heart Health Study who had obesity and severe OSA.²² For the 81 patients who were prescribed PAP therapy, the propensity-matched hazard ratio for all-cause mortality was 0.58 (95% CI, 0.35 to 0.96) compared to matched patients who did not receive a prescription for PAP. Survival curves indicated that the difference in mortality appeared 6 to 7 years after initiation of PAP. Exploratory analysis indicated that PAP might also be associated with a lower risk of cardiovascular mortality.

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.²³ In multivariate analysis, the risk of respiratory complications was increased for both diagnosed and undiagnosed OSA patients compared with controls (odds ratio, 2.08; p<.001). The risk of cardiovascular complications, primarily cardiac arrest and shock, was higher in OSA patients not diagnosed until after surgery (relative risk, 2.20; 95% CI, 1.16 to 4.17; p=.02), but not in those diagnosed prior to surgery (relative risk, 0.75; 95% CI, 0.43 to 1.28; p=.29); the difference between

groups was statistically significant ($p=.009$). There was a significant trend toward a higher risk with increasing OSA severity. Study limitations included the inability to determine whether CPAP was used perioperatively, and, because body mass index could not be determined, potential confounding from the close association between obesity and OSA.

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).²⁴ For the telemedicine arm of this randomized trial, as reported by Fox et al (2012), the research coordinator reviewed the transmitted data daily and contacted the patient if any of the following were present: mask leak greater than 40 L/min for more than 30% of the night, less than 4 hours of use for 2 consecutive nights, machine-measured AHI of more than 10 events per hour, and 90th percentile of pressure greater than 16 cm H₂O. Evaluation by their physician sleep specialist after 3 months of therapy showed a similar modest decrease in AHI for the 2 groups (1.6 for telemedicine vs 0.7 for controls).

Subsection Summary: Positive Airway Pressure Devices

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

Oral Appliances

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.²⁵ Meta-analysis showed that oral appliances reduced the AHI, arousal index, and Oxygen Desaturation Index, and increased 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 versus custom-made mandibular repositioning devices.²⁶ 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 3-month trial period. Patients used the custom-made device for more nights per week (7 vs 3, $p=.004$) and hours per night (5 vs 3, $p=.006$) than the ready-made device. Treatment response (AHI <5 events per hour) was obtained in 64% of patients during use of the custom-made device phase compared with a 24% response rate using the ready-made device ($p<.001$). Treatment failure (<50% reduction in AHI) was more frequent with the ready-made device (36%) than with the custom device (4%), while an ESS score of at least 10 was more frequent during the ready-made phase (66%) than with the custom-made phase (33%). An improvement in the QOL was observed only during the custom-made device phase.

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.⁴

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

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 Obstructive Sleep Apnea 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.²⁷ All patients had failed to comply with CPAP. Pre- and post-treatment AHI was assessed in a home sleep apnea test without the oral appliance. AHI decreased from a mean 45.9 events per hour to 16.5 ($p < .01$) 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.²⁸ Only patients who complied with oral appliance wear were included in the study. The mean AHI was reduced from 12.85 to 6.2 events per hour ($p < .001$) with the appliance, while the Oxygen Saturation Index improved from 6.3% to 2.6% ($p < .001$). Limitations of these studies included the use of a home sleep apnea test rather than the more accurate laboratory PSG, uncertain blinding of the physician evaluating the sleep study, the small number of patients studied, the lack of intention-to-treat analysis, and the lack of long-term follow-up.

Subsection Summary: Palate and Mandible Expansion

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.

Daytime sleep study (PAP-NAP)

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

Krakow et al (2008) reported on the use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP.²⁹ Patients had been referred by psychiatrists or primary care physicians for unspecified insomnia conditions, insomnia due to a mental disorder, or hypnotic dependence. Nearly all patients had anxiety, fear, and/or resistance regarding PAP therapy or the diagnosis of OSA. Thirty-nine patients who would not complete a titration protocol (full-night or split-night) were offered a daytime procedure (PAP-NAP) prior to night-time titration. The PAP-NAP protocol had 5 components: pretest instructions to maximize chances for daytime napping; introduction of PAP therapy addressing barriers to use; type 3 monitoring hookup (10 channels without electroencephalography leads); PAP therapy during 1 to 2 hours in bed in which the patient had the opportunity to fall asleep with the mask in place; and post-test follow-up. Thirty-five of 39 nap-tested patients subsequently scheduled and completed an overnight titration or split-night study with full PSG. The effect of the PAP-NAP intervention on compliance was compared with historical controls ($n=38$) who had insomnia, mental health conditions, and OSA with resistance to CPAP who completed titration. A prescription for PAP therapy was filled by 85% of the PAP-NAP group compared with 35% of controls. Regular use during a 30-day period was recorded by the PAP device in 67% of the intervention group and in 23% of controls. Adherence, defined as at least 5 days a week with an average of at least 4 hours a day, was 56% in the PAP-NAP group and 17% in controls.

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

time of follow-up 71% of patients who had initially refused PAP were considered users and 29% were non-users.

Subsection summary: PAP-NAP

The evidence on the PAP-NAP includes 1 comparative trial with historical controls and a case series of patients who were resistant to CPAP titration. These studies do not provide sufficient evidence to form conclusions on the efficacy of this approach in improving compliance with CPAP. The patient population in the comparative study was highly selected and the behavioral intervention may be dependent on the specific clinicians providing treatment. In addition, historical controls were used, and they were not well-matched to the study population. For these reasons, the internal validity and generalizability of the results are uncertain.

Nasal Expiratory Positive Airway Pressure

Evidence on nasal expiratory positive airway pressure (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.³¹ 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 3 months, the decrease in ESS score was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1-point difference in ESS score is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of 5 or more events per hour on the device-off PSG night. The oxygenation results (Oxygenation Desaturation Index and percent of total sleep time with oxygen saturation <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduction to less than 10 events per hour (if device-off AHI was ³10 events per hour), was greater in the EPAP group at 1 week (62% vs 27.2%) and at 3 months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and by 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing due to adverse events. Overall, the validity of these results was limited by the high dropout rate, and uncertainty of the clinical significance of the results.

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.³² 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 (N =920 patients) that had data on pre- and postnasal EPAP.³³ Study designs included 10 conference papers and 8 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 ($p<.001$). For 359 patients, ESS score modestly improved from 9.9 to 7.4 ($p<.001$). Data from the Berry et al (2011) RCT (described 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.³⁴ PSG with EPAP or a placebo device showed a significant mean improvement in Obstructive Apnea Index with EPAP (0.6 vs 4.2, $p=.01$), but responses varied (3 did not improve, 2 worsened). No other measures were statistically significant in this trial. For responders who used the devices at home for 30 days, adherence was 83% of nights. ESS scores improved from 11 to 7 ($p=.031$) and Obstructive Sleep Apnea-18 questionnaire scores improved from 50 to 39 ($p=.028$). Other outcome measures did not improve significantly.

Oral and OroNasal Pressure Therapy

Lai et al (2019) reported a study with 22 patients with OSA who were incomplete responders to an oral appliance (AHI > 5).³⁵ They were assessed with the oral appliance plus either an oral or an oronasal EPAP. Both the oral and oral/nasal devices were studied in the same night (split night PSG); the order of the EPAP devices was randomized. Power analysis indicated that 20 participants would be sufficient to detect a an AHI difference of 7 between conditions. Five patients (23%) had at least a 50% reduction in total AHI with the oral EPAP compared to the oral appliance alone, while 10 patients (45%) had a 50% reduction in AHI with the combined oral and nasal EPAP valves. Neither of these was statistically significant. Only 2 patients (9%) achieved an AHI of less than 5 with the oral EPAP device compared to 9 (41%) with the combined oral and nasal valves. However, sleep efficiency was disrupted with the oronasal EPAP valves.

Subsection Summary: Nasal Expiratory Positive Airway Pressure

The evidence on nasal 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. An oral EPAP device did not have significant benefit when added to an oral appliance.

eXciteOSA

eXciteOSA (previously named Snoozeal) is intended to reduce snoring and mild OSA by increasing tongue muscle tone with daytime neuromuscular electrical stimulation. Two prospective single arm studies were identified, both instructed participants to use the device for 20 min daily for 6 weeks. Objective sleep parameters were measured by a Watch-PAT and use was tracked by the accompanying smartphone app. The time snoring greater than 40 dB (all snoring) was a primary outcome. Subjective decrease in snoring by the bed partner was measured by a Visual Analogue Scale (VAS), and the ESS and the Pittsburg Sleep Quality Index (PSQI) were used to assess subjective sleepiness and quality of life.

Kotecha et al (2021) studied a prospective cohort of 75 habitual snorers who were treated with eXciteOSA.³⁶ Patients with a body mass index (BMI) greater than 35 and AHI greater than 15 were excluded. For the 70 patients who completed the study, snoring time measured by the Watch-PAT decreased by 48% and bed partners reported an average reduction in snoring of 40%. The mean AHI decreased from 5.94 to 5.37 events per hour. The PSQI improved by approximately 1 point for both the participants ($7.03 + 3.13$ to $5.92 + 2.83$, $p =.004$) and bed partners ($7.35 + 2.76$ to $6.33 + 2.80$, $p =.029$). In the 38 patients with mild OSA, AHI was reduced from 9.8 to 4.7 events/h, and the ESS improved from 9.0 to 5.1 ($p<.001$). Compliance with the protocol as measured by the app ranged from 59.5% to 95.2% (mean utilization 83.3%).

In a study by Baptista et al (2021), eXciteOSA was administered to 125 patients with a complaint of snoring and an AHI less than 15 (no more than mild OSA), 50 participants had an AHI of less than 5 and were considered primary snorers.³⁷ Only 1 participant withdrew due to inability to tolerate the treatment (gag reflex), and 115 participants completed the trial (92%). The mean reduction in the proportion of time with moderate or greater snoring decreased from 30.41% to 17.87% (41% reduction, $p < .001$). Bed-partner-reported snoring decreased from 6.1 to 3.7 ($p < .001$). ESS improved from 8.4 to 5.8 and the PSQI improved for both the participants (7.16 to 5.75, $p < .001$, 95% CI 0.89–1.92) and bed partners (6.87 to 5.94, $p = .02$, 95% CI 0.15–1.68). The AHI was reduced from 6.85 to 5.01 ($p < .001$), a difference that is not clinically significant.

Subsection Summary: eXciteOSA

No controlled trials on eXciteOSA were identified. The evidence includes 2 prospective single arm studies in patients with primary snoring or mild OSA. The available evidence suggests that when used for 20 min a day over 6 weeks, the treatment may reduce snoring. In the overall population, the effects on AHI were not clinically significant. For the subgroup of patients with mild OSA, the improvement in AHI in these uncontrolled trials remained modest. With a mean ESS of less than 10, this group of patients might not be considered symptomatic. Controlled studies are needed to evaluate whether patients who meet criteria for treatable OSA improve and whether individuals would continue use after the 6 week trial period.

NightBalance Sleep Position Trainer

Meta-analyses

For some patients, apneic events occur predominantly when the individual is supine. Sleep position trainers for individuals with positional OSA are intended to reduce time on the back and can range from supine vibration alarm devices to tennis balls sewn into the back of night wear. A Cochrane review by Srijithesh et al (2019) evaluated positional therapy for obstructive sleep apnea.³⁸ The meta-analysis included 3 crossover studies with a vibration alarm and 5 with specially designed pillows or semi-rigid backpacks. The review found low to moderate evidence that CPAP was more effective than positional therapy in improving AHI ($n=72$), but positional therapy was more effective than no treatment for improving outcomes ($n=251$) and may have better adherence than CPAP. All of the studies were short-term and the long-term effect was uncertain.

Randomized Controlled Trials

Several RCTs have been reported on the FDA-cleared NightBalance Sleep Position Training device. The device vibrates when it detects a supine position and the vibration increases gradually until the individual changes position. Characteristics and results of RCTs are described in Tables 5 and 6. Limitations of the trials are described in Tables 7 and 8.

Eijsvogel et al (2015) compared the first generation sleep position trainer to "the tennis ball technique" with commercially available air pillows on the back in 55 participants.³⁹ Both devices reduced supine position by a median of 100% and reduced the median supine AHI to 0 events/h at the 1 month sleep study. There were no significant differences between the groups for the ESS, VAS, and sleep-related quality of life data. Objective compliance data for the entire month showed that the median hours used per night was numerically higher but did not achieve statistical significance due to variability (6.5 vs 4.5, $p = .078$). There were significant increases in the percentage of patients who used the device every day (51.7% vs 15.4%, $p = .005$) and in effective compliance, measured by use for at least 4 hours per night on at least 5 days per week (75.9% vs 42.3%, $p = .011$). Compliance in both groups decreased over the month of the study. Continued use after the month trial was not evaluated, and the clinical significance of an increase in compliance without a difference in sleepiness or quality of life is uncertain.

de Ruiter et al (2018) evaluated 12 month efficacy of the NightBalance Sleep Position Trainer compared to oral appliance therapy in a multicenter randomized trial of participants with positional OSA.⁴⁰ This was a follow-up to a previously published 3-month study. There were no

significant differences between the 2 groups in AHI, ESS, FOSQ, or the average hours of use per night. However, 41% of the participants had dropped out of the study by the 12 month follow-up due to adverse events or lack of efficacy, and results in the publication represent only those individuals who had remained in the study. Sensitivity analysis with intention-to-treat was reported in a supplement, and in the worst case scenario, AHI decreased by 1 with NightBalance and by 5.5 with the oral appliance. With intention-to-treat and last observation carried forward, the average hours of use per night decreased to 3.1 for NightBalance and 2.7 for the oral appliance ($p=.522$).

Berry et al (2019) compared the NightBalance Sleep Position Trainer to APAP in a 6-week randomized crossover trial in treatment naive patients (N=117) with exclusive positional OSA.⁴¹ The investigators selected a non-inferiority margin of 5 events/h for the AHI endpoint and 30 minutes for adherence. The sleep position trainer achieved non-inferiority with a difference of 3.58 events/h. APAP was more effective than the Sleep Position Trainer in terms of the AHI ($p<.001$), but adherence was better with NightBalance ($p <.001$). There were no significant differences between the treatments for total sleep time, sleep efficiency, sleep latency, wake after sleep onset, or the duration of sleep stages. The ESS was statistically better in the APAP phase, although this did not achieve clinical significance. Post-hoc analysis of participants who had a baseline ESS score of greater than 10 showed that while both treatments improved the ESS, APAP was more effective (final ESS: 9.5 vs 11.5, $p<.001$). Patients reported that the NightBalance device was easier to use and more comfortable and would choose this device, but thought that APAP was more effective in treating the sleep apnea.

Table 5. Summary of Key RCT Characteristics

| Study; Trial | Countries | Sites | Design | Participants | Interventions ¹ | |
|--|-----------|-------|-------------------------|--|--|---|
| Eijsvogel et al (2015) ³⁹ | EU | | Randomized parallel arm | 55 patients with mild to moderate symptomatic POSA who had been referred to a tertiary care center | Active 4 weeks with the first generation NightBalance Sleep Position Trainer (n=29) | Comparator 4 weeks with commercially available inflated airbags on the back (n=26) |
| de Ruiter et al (2018) ⁴⁰ | EU | 2 | Randomized parallel arm | 99 patients with mild to moderate POSA, defined as AHI ≥ 2 times nonsupine AHI and total AHI < 15 events/h | 12 mo follow-up with NightBalance Sleep Position Trainer (n=48, 29 completed) | 12 mo follow-up with OAT with an imbedded microchip to monitor usage (n=51, 29 completed) |
| Berry et al (2019) ⁴¹ (POSActive) | US | 11 | Randomized crossover | 117 treatment naive patients with exclusive POSA, defined as a supine AHI ≥ 2 times nonsupine AHI and a nonsupine AHI < 10 events/h; total AHI was at least 15 events/h (moderate to severe OSA). | 6 weeks with the NightBalance Sleep Position Trainer | 6 weeks with APAP |

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

¹ Number randomized; intervention; mode of delivery; dose (frequency/duration).

Table 6. Summary of Key RCT Results

| Study | AHI (sd) | Adherence (sd) | ESS (sd) | Quality of Life (sd) |
|--------------------------------------|----------|----------------------|----------|----------------------|
| Eijsvogel et al (2015) ³⁹ | | Hours per Night (sd) | | QSQ (sd) |
| N | 48 | 55 | 48 | 48 |

| Study | AHI (sd) | Adherence (sd) | ESS (sd) | Quality of Life (sd) |
|--------------------------------------|-----------------|----------------------|-------------|----------------------|
| NightBalance | 3.9 (0.4–30.8) | 6.5 (5.5–7.2) | 6.0 ± 3.6 | 5.4 ± 1.2 * |
| TBT | 5.8 (0.2–23.1) | 4.5 (1.1–7.0) | 7.8 ± 4.3 | 4.8 ± 1.3 |
| p | | .078 | | |
| de Ruiten et al (2018) ⁴⁰ | 12 mo follow-up | Hours per Night (sd) | | FOSQ (sd) |
| N | 58 | 57 | 46 | 30 |
| NightBalance | 7.1 | 5.2 (2.2) | 7.0 | 19.0 |
| OAT | 5.0 | 5.0 (2.0) | 4.0 | 17.7 |
| p | .792 | .743 | .073 | .864 |
| Berry et al (2019) ⁴¹ | | Minutes per Night | | |
| (POSAtive) | | | | |
| NightBalance | 7.29 (6.8) | 345.3 (111.22) | 8.27 (4.98) | 17.32 (2.18) |
| CPAP | 3.71 (5.1) | 286.98 (128.9) | 7.37 (3.98) | 17.62 (1.87) |
| p | <.001 | <.001 | .007 | .058 |

AHI: apnea/hypopnea index; CPAP: continuous positive airway pressure; ESS: Epworth sleepiness scale; FOSQ: functional outcomes of sleep questionnaire; OAT: oral appliance therapy; RCT: randomized controlled trial; SF-36: short-form 36; TBT: tennis ball technique (airbags); QSQ: Quebec Sleep Questionnaire.

Table 7. Study Relevance Limitations

| Study | Population ^a | Intervention ^b | Comparator ^c | Outcomes ^d | Duration of Follow-up ^e |
|---|--|---------------------------------------|-------------------------|-----------------------|---|
| Eijsvogel et al (2015) ³⁹ | 4. Not all patients would have qualified for treatment. The mean score on the Epworth Sleepiness Score was < 10. | 4. This was a first generation device | | | 1. There was no long-term follow-up after the 4 week intervention |
| de Ruiten et al (2018) ⁴⁰ | | | | | |
| Berry et al (2019) ⁴¹ (POSAtive) | | | | | 1. There was no long-term follow-up after the 6 week cross-over phases. |

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

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

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

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

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

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

Table 8. Study Design and Conduct Limitations

| Study | Allocation ^a | Blinding ^b | Selective Reporting ^c | Data Completeness ^d | Power ^e | Statistical ^f |
|--------------------------------------|-----------------------------------|---|---|---|--------------------|--------------------------|
| Eijsvogel et al (2015) ³⁹ | 3. Allocation concealment unclear | 1, 2. Participants could not be blinded to treatment assignment and could bias the subjective measures. | | 6. Not intent to treat analysis | | |
| de Ruiten et al (2018) ⁴⁰ | 3. Allocation concealment unclear | 1, 2. Participants could not be blinded to treatment assignment. | 2. Patients lost to follow-up were not counted as treatment failures in the | 1, 2. High loss to follow-up; 59% of patients completed the study | | |

| Study | Allocation ^a | Blinding ^b | Selective Reporting ^c | Data Completeness ^d | Power ^e | Statistical ^f |
|---|-----------------------------------|--|----------------------------------|--------------------------------|--------------------|--------------------------|
| Berry et al (2019) ⁴¹ (POSAtive) | 3. Allocation concealment unclear | 1, 2. Participants could not be blinded to treatment assignment. | primary analysis. | | | |

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

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

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

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

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

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

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

Observational Studies

Van Maanen and de Vries (2014) conducted a prospective study in patients with mild to moderate positional OSA.⁴² There were 145 patients who were asked to use the Sleep Position Trainer for 6 months with the option to keep the device at the end of the study. However, the data could not be retrieved in 39 patients, leaving 106 with objective data. The time spent supine decreased from 21% at baseline to 3% in the 53 participants (36%) who provided objective measurements at 6 months. Subjective measures (median ESS 11 to 8; PSQI 8 to 6; and FOSQ 87 to 103) were significantly improved compared to baseline, but only 66 participants out of the 145 (45%) completed the questionnaires. Analysis was per protocol rather than intent-to-treat, raising questions about the validity of the results. Regular use, defined as at least 4 hours a night over at least 5 nights, was 71.2% averaged over the trial period. Objective use of the device for at least 1 hour per night decreased from 106 patients at the start of the study to less than 60 by 6 months. It is uncertain whether the number of patients using the device would be as high as this outside of a trial.

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

Subsection Summary: NightBalance Sleep Position Trainer

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

Summary of Evidence**Diagnosis**

For individuals who have suspected OSA who receive home sleep apnea testing with at least 3 recording channels, the evidence includes RCTs. 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 an I 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. 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 that the technology results in an improvement in the net health outcome.

Treatment

For individuals who have OSA who receive PAP devices or oral appliances, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. 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 an I improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments (e.g., palate expansion, EPAP, oral pressure therapy, tongue stimulation, supine vibration), the evidence includes RCTs, prospective single arm studies, and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on nasal EPAP devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, 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 small RCT with 22 patients found no benefit of an oral EPAP therapy device when added to an oral appliance. One comparative trial with historical controls and a retrospective chart review evaluated PAP-NAP to reduce resistance to CPAP titration or use. Additional study is needed to evaluate the efficacy of this intervention.

Single arm studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is of uncertain. Several RCTs have been published with a sleep positioning device that vibrates when the individual is in a supine position. Drop-out rates were high and long-term compliance is unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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

2014 Input

In response to requests, input was received from 7 physician specialty societies (8 reviewers) and 4 academic medical centers (6 reviewers) while this policy was under review in 2014. Input focused on the routine screening of patients scheduled to undergo bariatric surgery. There was a consensus that routine screening is considered medically necessary in this population due to the high prevalence of obstructive sleep apnea (OSA) in patients with a body mass index greater than 40 kg/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, input was received from 1 physician specialty society and 6 academic medical centers (8 reviewers) while this policy was under review in 2010. Input focused on the sensors required for unattended home sleep studies and on diagnosis and treatment of OSA in children. In general, reviewers supported the requirement that home monitors measure 4 parameters, including respiratory effort, airflow, and oxygen saturation, and their use is restricted to adults. Some exceptions were noted for specific situations. The 2010 update included recommendations from reviewers on indications specific to pediatric patients.

2009 Input

In response to requests, input was received from 5 physician specialty societies (6 reviewers) and 3 academic medical centers while this policy was under review in 2009. Professional society guidelines and position statements were also reviewed. In general, input supported the use of polysomnography, 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

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

American Academy of Sleep Medicine

In 2017, the American Academy of Sleep Medicine (AASM) published clinical practice guidelines on diagnostic testing for adult OSA.⁴⁵ AASM provided the following recommendations (Table 9).

Table 9. Recommendations on Diagnostic Testing for Adult OSA

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

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

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.⁴⁶ 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; or a bed partner describing loud snoring, breathing interruptions, or both.

- o In laboratory polysomnography (standard) records electroencephalogram, electrooculogram, chin electromyogram, airflow, oxygen saturation, respiratory effort, and heart rate.
- o 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).
- Autotitrating 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.^{11,12} "A STRONG (i.e., "We recommend...") recommendation is one that clinicians should follow under most circumstances. A CONDITIONAL recommendation (i.e., "We suggest...") reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients."

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

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

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

- Use of PAP to treat OSA in adults with impaired sleep-related quality of life.
- 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.²⁵ The 2 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.

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.^{47,48} AAP recommended that all children or adolescents be screened for snoring, and PSG is performed in children or adolescents with snoring and symptoms or signs of OSA as listed in the guideline. If PSG is not available, an alternative diagnostic test or referral to a specialist may be considered (option). The estimated prevalence rates of OSA in children or adolescents ranged from 1.2% to 5.7%. Adenotonsillectomy was recommended as the first-line treatment for patients with adenotonsillar hypertrophy, and patients should be reassessed clinically postoperatively to determine whether additional treatment is required. High-risk patients should be reevaluated with an objective test or referred to a sleep specialist. CPAP was recommended if adenotonsillectomy was not performed or if OSA persisted postoperatively. Weight loss was recommended in addition to other therapy in patients who are overweight or obese, and intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

American Society of Metabolic and Bariatric Surgery

The American Society of Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA (reviewed in October 2015).⁴⁹ The guidelines noted that while some reports in the literature have recommended routine screening for OSA prior to bariatric surgery, other reports have suggested clinical screening only does not result in any increase in postoperative pulmonary complications after laparoscopic Roux-en-Y gastric bypass, and that most current surgical practices refer patients with clinical symptoms of OSA for PSG, but do not make this a routine preoperative test prior to bariatric surgery. The Society provided, based on the evidence in the literature to date, the following guidelines on OSA in the bariatric surgery patient and its perioperative management:

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

American Academy of Otolaryngology-Head and Neck Surgery

In 2017, the American Academy of Otolaryngology-Head and Neck Surgery published a position statement on the treatment of obstructive sleep apnea.⁵⁰ The academy states that tonsillectomy and adenoidectomy is the first line treatment in pediatric OSA. In most adults, CPAP is the first line treatment. Surgical procedures may be considered when PAP therapy is inadequate.

American Thoracic Society

The American Thoracic Society (2016) published a research statement on the long-term effects and treatment of mild OSA in adults.⁵¹ The Society's systematic review concluded:

- 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 for 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."[52,53](#).

Medicare National Coverage

In 2001, the Centers for Medicare & Medicaid Services published a decision memorandum on CPAP that addressed how to define moderate-to-severe OSA as a guide to a coverage policy for CPAP. This review of the literature suggested there is a risk of hypertension with an AHI greater than 15 events per hour, and thus treatment would be warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 events per hour and associated symptoms, CMS concluded that the data from 3 randomized controlled trials demonstrated improved daytime somnolence and functioning in those treated with CPAP. In 2008, CMS expanded coverage of CPAP to include those beneficiaries with a diagnosis of OSA made with a combination of clinical evaluation and unattended home sleep monitoring using a device with at least 3 channels.[54,55](#) 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 thoracoabdominal movement or airflow as compared to baseline and with at least a 4% oxygen desaturation.

8. Coverage with Evidence Development (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address 1 or more of the following questions:
 - 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.⁵⁶ 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 3 or more channels, 1 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 3 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 2021 identified over 300 ongoing studies on diagnosis and medical management of OSA.

Appendix 1

Obstructive Sleep Apnea Oral Appliance Therapy Check-off List:

Date of pre-authorization request: _____

Name of patient: _____

Blue Shield of California number: _____

The following are a summary of my clinical findings:

1. AHI = 15+: Yes ____ No ____
2. RDI = 15+: Yes ____ No ____ N/A ____
3. ESS = 10+: Yes ____ No ____ N/A ____
4. AHI or RDI <15 but >=5 with hypertension or ESS >10: Yes:____ No____

- 5. Evidence of periodontal disorder: Yes ____ No ____
- 6. Evidence of temporomandibular disorder: Yes ____ No ____
- 7. Oral appliance is custom-made device by DDS: Yes ____ No ____
- 8. Physician prescription for oral device is attached: Yes ____ No ____
- 9. Acceptable Sleep study attached (less than 5 years old): Yes ____ No ____
- 10. CPAP intolerance (Affidavit) form or statement indicating the patient refuses to use CPAP attached: Yes ____ No ____
- 11. Patient undergoing orthodontic therapy: Yes ____ No ____

Explanation/Comments

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

Signature: _____ Date: _____

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Documentation for Clinical Review

Sleep Studies

Please provide the following documentation:

- Type of sleep study that is being requested
- Reason for requested study
- Completed sleep questionnaires (e.g., Epworth Sleepiness Scale, Berlin Questionnaire, STOP-Bang) if applicable
- Prior Polysomnography or Sleep study reports; if applicable
- Name and type of device used for home sleep study if applicable

CPAP and APAP

Please provide the following documentation:

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

Intraoral Appliances

Please provide the following documentation:

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

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

- Polysomnography or Home Sleep study reports

Coding

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

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

| Type | Code | Description |
|------|-------|--|
| CPT® | 21083 | Impression and custom preparation; palatal lift prosthesis |
| | 21089 | Unlisted maxillofacial prosthetic procedure |
| | 21110 | Application of interdental fixation device for conditions other than fracture or dislocation, includes removal |
| | 21299 | Unlisted craniofacial and maxillofacial procedure |
| | 70486 | Computed tomography, maxillofacial area; without contrast material |
| | 70487 | Computed tomography, maxillofacial area; with contrast material(s) |
| | 76380 | Computed tomography, limited or localized follow-up study |
| | 94660 | Continuous positive airway pressure ventilation (CPAP), initiation and management |
| | 94762 | Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure) |
| | 95782 | Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist |
| | 95783 | Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist |
| | 95800 | Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (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) |
| | 95805 | Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness |
| | 95806 | Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement) |
| | 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 |
| | 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 |

| Type | Code | Description |
|-------|-------|---|
| | 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 a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 15-29 minutes of total time is spent on the date of the encounter. |
| | 99203 | Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 30-44 minutes of total time is spent on the date of the encounter. |
| | 99204 | Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 45-59 minutes of total time is spent on the date of the encounter. |
| | 99205 | Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60-74 minutes of total time is spent on the date of the encounter. |
| | 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. (Code revision effective 1/1/2022) |
| | 99212 | Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter. |
| | 99213 | Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20-29 minutes of total time is spent on the date of the encounter. |
| | 99214 | Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30-39 minutes of total time is spent on the date of the encounter. |
| | 99215 | Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 40-54 minutes of total time is spent on the date of the encounter. |
| HCPCS | A7027 | Combination oral/nasal mask, used with continuous positive airway pressure device, each |

| Type | Code | Description |
|------|-------|--|
| | A7028 | Oral cushion for combination oral/nasal mask, replacement only, each |
| | A7029 | Nasal pillows for combination oral/nasal mask, replacement only, pair |
| | A7034 | Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap |
| | A7035 | Headgear used with positive airway pressure device |
| | A7036 | Chinstrap used with positive airway pressure device |
| | A7037 | Tubing used with positive airway pressure device |
| | A7038 | Filter, disposable, used with positive airway pressure device |
| | A7039 | Filter, nondisposable, used with positive airway pressure device |
| | A7047 | Oral interface used with respiratory suction pump, each |
| | D9947 | Custom sleep apnea appliance fabrication and placement (Code effective 1/1/2022) |
| | D9948 | Adjustment of custom sleep apnea appliance (Code effective 1/1/2022) |
| | D9949 | Repair of custom sleep apnea appliance (Code effective 1/1/2022) |
| | E0470 | Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device) |
| | E0471 | Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device) |
| | E0485 | Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment |
| | E0486 | Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment |
| | E0561 | Humidifier, nonheated, used with positive airway pressure device |
| | E0562 | Humidifier, heated, used with positive airway pressure device |
| | E0601 | Continuous positive airway pressure (CPAP) device |
| | G0398 | Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation |
| | G0399 | Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation |
| | G0400 | Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels |
| | K1001 | Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type |
| | K1027 | Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment |
| | K1028 | Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application (Code effective 4/1/2022) |
| | K1029 | Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and |

| Type | Code | Description |
|------|------|---|
| | | control electronics unit, controlled by phone application, 90-day supply (Code effective 4/1/2022) |

Policy History

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

| Effective Date | Action |
|----------------|--|
| 04/03/2009 | Policy title change Policy revision with position change Policy combined: <ul style="list-style-type: none"> Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome Obstructive Sleep Apnea Surgeries |
| 06/18/2009 | Administrative Review |
| 01/19/2010 | Coding Update |
| 10/01/2010 | Policy title change from Diagnosis and Treatment Services for Obstructive Sleep Apnea (OSA) and Upper Airway Resistance Syndrome (UARS) Policy revision with position change |
| 01/21/2011 | Coding Update |
| 04/12/2011 | Coding Update |
| 07/22/2011 | Policy revision with position change |
| 08/10/2011 | Administrative Update |
| 01/11/2013 | Policy criteria clarification and revision |
| 02/22/2013 | Coding Update |
| 07/03/2013 | Policy criteria clarification and revision |
| 01/30/2015 | Policy title change from Obstructive Sleep Apnea - Diagnosis and Management Policy revision with position change effective 3/30/2015 |
| 03/30/2015 | Policy revision with position change |
| 08/31/2015 | Coding update |
| 02/01/2016 | Policy revision without position change |
| 03/01/2016 | Policy Guideline clarification |
| 02/01/2017 | Policy revision without position change |
| 10/01/2017 | Policy revision without position change |
| 06/01/2018 | Policy revision without position change |
| 08/01/2018 | Policy revision without position change |
| 02/01/2019 | Documentation for Clinical Review clarification |
| 10/01/2019 | Policy revision without position change |
| 03/01/2020 | Coding update |
| 05/01/2020 | Administrative update. Policy statement and guidelines updated. |
| 06/01/2020 | Administrative update. Policy statement and guidelines updated. |
| 09/01/2020 | Annual review. Policy statement and literature updated. |
| 11/01/2020 | Administrative update. Policy statement and guidelines updated. |
| 12/01/2020 | Administrative update. Policy statement updated. |
| 01/01/2021 | Coding update. |
| 08/01/2021 | Annual review. Policy statement, guidelines and literature updated. |
| 09/01/2021 | Administrative update. |
| 11/01/2021 | Coding update. |
| 03/01/2022 | Coding update. |
| 07/01/2022 | Coding and Administrative update. |

Definitions of Decision Determinations

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

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

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

Prior Authorization Requirements (as applicable to your plan)

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

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

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

Appendix A

| POLICY STATEMENT | |
|---|---|
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| <p>Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome 2.01.18</p> <p>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 obstructive sleep apnea (OSA) in adults unless contraindicated.</p> <p>Prior authorization is not required for HSATs. However, treatment based on HSAT results will not be approved unless the following criteria are met:</p> <ol style="list-style-type: none"> I. Documentation that the device used meets the following criteria: <ol style="list-style-type: none"> A. A minimum of 3 recording channels with all of the following sensors: <ol style="list-style-type: none"> 1. Nasal pressure 2. Chest and abdominal respiratory inductance plethysmography 3. Oximetry; OR B. Utilization of Peripheral Arterial Tone (PAT) with oximetry and actigraphy C. The patient is at least 18 years old D. There are no contraindications to a home sleep study <p>Supervised Polysomnography (PSG) in a Sleep Laboratory 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 when appropriate unless documentation is provided why it cannot or was not done.</p> | <p>Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome 2.01.18</p> <p>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 obstructive sleep apnea (OSA) in adults unless contraindicated.</p> <p>Prior authorization is not required for HSATs. However, treatment based on HSAT results will not be approved unless the following criteria are met:</p> <ol style="list-style-type: none"> I. Documentation that the device used meets the following criteria: <ol style="list-style-type: none"> A. A minimum of 3 recording channels with all of the following sensors: <ol style="list-style-type: none"> 1. Nasal pressure 2. Chest and abdominal respiratory inductance plethysmography 3. Oximetry; OR B. Utilization of Peripheral Arterial Tone (PAT) with oximetry and actigraphy C. The patient is at least 18 years old D. There are no contraindications to a home sleep study <p>Supervised Polysomnography (PSG) in a Sleep Laboratory 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 when appropriate unless documentation is provided why it cannot or was not done.</p> |

POLICY STATEMENT

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| <p>An initial supervised polysomnography (PSG) performed in a sleep laboratory may be considered medically necessary for a patient with a moderate or high pretest probability of OSA in any of the following situations:</p> <ul style="list-style-type: none"> I. A previous home study failed to establish the diagnosis of OSA in a patient with a high pretest probability of OSA II. A previous home study was technically inadequate III. Failure of resolution of symptoms or recurrence of symptoms during treatment IV. Presence of a known comorbidity (a contraindication to HSAT) that might alter ventilation or decrease the accuracy of a home sleep apnea test, including, but not limited to significant, ongoing symptoms 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 arrhythmias V. 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) VI. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA VII. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed VIII. Pediatric patient (i.e., less than 18 years of age) <p>A repeated, supervised polysomnography (PSG) performed in a sleep laboratory may be considered medically necessary for a patient with a moderate or high pretest probability of OSA in any of the following situations:</p> <ul style="list-style-type: none"> I. To initiate and titrate CPAP for an adult patient who has clinically significant OSA II. Failure of resolution of symptoms or recurrence of symptoms during treatment III. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA | <ul style="list-style-type: none"> I. An initial supervised polysomnography (PSG) performed in a sleep laboratory may be considered medically necessary for a patient with a moderate or high pretest probability of OSA in any of the following situations: <ul style="list-style-type: none"> A. A previous home study failed to establish the diagnosis of OSA in a patient with a high pretest probability of OSA B. A previous home study was technically inadequate C. Failure of resolution of symptoms or recurrence of symptoms during treatment D. Presence of a known comorbidity (a contraindication to HSAT) that might alter ventilation or decrease the accuracy of a home sleep apnea test, including, but not limited to significant, ongoing symptoms 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 arrhythmias E. 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) F. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA G. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed H. Pediatric patient (i.e., less than 18 years of age) II. A repeated, supervised polysomnography (PSG) performed in a sleep laboratory may be considered medically necessary for a patient with a moderate or high pretest probability of OSA in any of the following situations: <ul style="list-style-type: none"> A. To initiate and titrate CPAP for an adult patient who has clinically significant OSA B. Failure of resolution of symptoms or recurrence of symptoms during treatment C. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA |

POLICY STATEMENT

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| <p>IV. 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)</p> <p>V. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed</p> <p>VI. To assess efficacy of adenotonsillectomy for a patient under the age of 18</p> <p>VII. To initiate and titrate CPAP for a child with either of the following:</p> <p>A. An AHI or RDI of greater than or equal to 5 events per hour</p> <p>B. 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</p> <p>Auto-adjusting positive airway pressure (APAP) may be considered medically necessary for the titration of pressure as an alternative to a CPAP titration PSG or CPAP use in adults with clinically significant OSA.</p> <p>Medical Management CPAP (or APAP) 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 diagnostic study.</p> <p>Bilevel positive airway pressure (BiPAP) may be considered medically necessary with both of the following:</p> <p>I. Patient has clinically significant OSA</p> <p>II. Patient failed a prior trial of CPAP or whom BiPAP is found to be more effective in the sleep lab</p> <p>Replacement of a PAP device after the warranty period (usually 2-5 years) may be considered medically necessary with all of the following:</p> <p>I. Documentation that the device is no longer functioning properly</p> <p>II. Documentation of clinically significant OSA (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> | <p>D. 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)</p> <p>E. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed</p> <p>F. To assess efficacy of adenotonsillectomy for a patient under the age of 18</p> <p>G. To initiate and titrate CPAP for a child with either of the following:</p> <p>1. An AHI or RDI of greater than or equal to 5 events per hour</p> <p>2. 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</p> <p>III. Auto-adjusting positive airway pressure (APAP) may be considered medically necessary for the titration of pressure as an alternative to a CPAP titration PSG or CPAP use in adults with clinically significant OSA.</p> <p>Medical Management</p> <p>IV. CPAP (or APAP) 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 diagnostic study.</p> <p>V. Bilevel positive airway pressure (BiPAP) may be considered medically necessary with both of the following:</p> <p>A. Patient has clinically significant OSA</p> <p>B. Patient failed a prior trial of CPAP or whom BiPAP is found to be more effective in the sleep lab</p> <p>VI. Replacement of a PAP device after the warranty period (usually 2-5 years) may be considered medically necessary with all of the following:</p> |

POLICY STATEMENT

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| <p>III. Documentation of current compliance prior to the problem with the machine</p> <p>IV. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</p> <p>V. Documentation the device is out of warranty</p> <p><u>Replacement of a PAP device</u> within the warranty period may be considered medically necessary with all of the following:</p> <p>I. Documentation that the device is no longer functioning properly</p> <p>II. Documentation of <u>clinically significant OSA</u> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> <p>III. Documentation of current compliance prior to the problem with the machine</p> <p>IV. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</p> <p>V. Documentation that the cost of repairs would exceed that of replacement</p> <p>A single oral appliance (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in adults with <u>clinically significant OSA</u> when all of the following conditions have been met:</p> <p>I. Initial or continued use of CPAP is <u>clinically not tolerated or is refused by the patient</u></p> <p>II. The device is prescribed by a treating physician</p> <p>III. The device is custom-fitted by qualified dental personnel</p> <p>IV. There is documentation of absence of temporomandibular dysfunction or periodontal disease</p> <p>V. Physician has reviewed, completed and signed an <u>OSA Oral Appliance Therapy Check-off List</u> (signed copy attached to request)</p> <p><u>Replacement of an oral appliance</u> (OA) after the warranty period (usually 3 years) may be considered medically necessary with all of the following:</p> | <p>A. Documentation that the device is no longer functioning properly</p> <p>B. Documentation of <u>clinically significant OSA</u> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> <p>C. Documentation of current compliance prior to the problem with the machine</p> <p>D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</p> <p>E. Documentation the device is out of warranty</p> <p>VII. <u>Replacement of a PAP device</u> within the warranty period may be considered medically necessary with all of the following:</p> <p>A. Documentation that the device is no longer functioning properly</p> <p>B. Documentation of <u>clinically significant OSA</u> (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> <p>C. Documentation of current compliance prior to the problem with the machine</p> <p>D. Documentation of benefit from the device (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</p> <p>E. Documentation that the cost of repairs would exceed that of replacement</p> <p>VII. A single oral appliance (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in adults with <u>clinically significant OSA</u> when all of the following conditions have been met:</p> <p>A. Initial or continued use of CPAP is <u>clinically not tolerated or is refused by the patient</u></p> <p>B. The device is prescribed by a treating physician</p> <p>C. The device is custom-fitted by qualified dental personnel</p> <p>D. There is documentation of absence of temporomandibular dysfunction or periodontal disease</p> |

POLICY STATEMENT

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| <p>I. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate</p> <p>II. Documentation of clinically significant OSA (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> <p>III. Documentation of current compliance prior to the problem with the OA</p> <p>IV. Documentation of benefit from the use of the OA (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</p> <p>V. Physician has reviewed, completed and signed an OSA Oral Appliance Therapy Check-off List (signed copy attached to request)</p> <p>Replacement of an oral appliance (OA) <i>within</i> the warranty period may be considered medically necessary with all of the following:</p> <p>I. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate</p> <p>II. Documentation of clinically significant OSA (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> <p>III. Documentation of current compliance prior to the problem with the OA</p> <p>IV. Documentation of benefit from the use of the OA</p> <p>V. Documentation that the cost of repairs would exceed that of replacement</p> <p>VI. Physician has reviewed, completed and signed an OSA Oral Appliance Therapy Check-off List (signed copy attached to request)</p> <p>Replacement of an oral appliance due to changes in dental alignment may be considered medically necessary with all of the following:</p> <p>I. Documentation of clinically significant OSA (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> | <p>E. Physician has reviewed, completed and signed an OSA Oral Appliance Therapy Check-off List (signed copy attached to request in addition to appropriate medical record documentation supporting the check list)</p> <p>IX. Replacement of an oral appliance (OA) <i>after</i> the warranty period (usually 3 years) may be considered medically necessary with all of the following:</p> <p>A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate</p> <p>B. Documentation of clinically significant OSA (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> <p>C. Documentation of current compliance prior to the problem with the OA</p> <p>D. Documentation of benefit from the use of the OA (improved daytime sleepiness or other symptoms; improved hypertension control, etc.)</p> <p>E. Physician has reviewed, completed and signed an OSA Oral Appliance Therapy Check-off List (signed copy attached to request)</p> <p>X. Replacement of an oral appliance (OA) <i>within</i> the warranty period may be considered medically necessary with all of the following:</p> <p>A. Documentation that the OA is no longer functioning properly including, but not limited to quality photographic evidence if appropriate</p> <p>B. Documentation of clinically significant OSA (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided)</p> <p>C. Documentation of current compliance prior to the problem with the OA</p> <p>D. Documentation of benefit from the use of the OA</p> <p>E. Documentation that the cost of repairs would exceed that of replacement</p> |

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| <ul style="list-style-type: none"> II. Physician has reviewed, completed and signed an OSA Oral Appliance Therapy Check-off List (signed copy attached to request) III. Initial or continued use of CPAP is not tolerated or is refused by the patient IV. The device is prescribed by a treating physician V. The device is custom fitted by qualified dental personnel VI. There is documentation of absence of significant temporomandibular dysfunction and periodontal disease VII. Needed after completion of orthodontic treatment that was prescribed and supervised by an orthodontist <p>The following are considered investigational:</p> <ul style="list-style-type: none"> I. Nasal expiratory positive airway pressure II. Oral pressure therapy devices III. Mandibular/palatal expansion devices for the treatment of OSA IV. The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) V. The use of a sleep positioning trainer with vibration VI. The use of daytime electrical stimulation of the tongue VII. The use of CPAP, bi-level positive airway pressure, APAP, ASV and intraoral appliances that do not meet the above criteria for the treatment of OSA VIII. Unattended home sleep apnea test for a child (younger than 18 years of age) IX. Multiple sleep latency testing (MSLT) in the initial workup (diagnosis) of OSA X. Mandibular repositioning (daytime), bruxism and anti-snoring oral appliances for the treatment of OSA | <ul style="list-style-type: none"> F. Physician has reviewed, completed and signed an OSA Oral Appliance Therapy Check-off List (signed copy attached to request) <p>XI. Replacement of an oral appliance due to changes in dental alignment may be considered medically necessary with all of the following:</p> <ul style="list-style-type: none"> A. Documentation of clinically significant OSA (a repeat sleep apnea test is not required if prior test results showing the need for the device is provided) B. Physician has reviewed, completed and signed an OSA Oral Appliance Therapy Check-off List (signed copy attached to request) C. Initial or continued use of CPAP is not tolerated or is refused by the patient D. The device is prescribed by a treating physician E. The device is custom fitted by qualified dental personnel F. There is documentation of absence of significant temporomandibular dysfunction and periodontal disease G. Needed after completion of orthodontic treatment that was prescribed and supervised by an orthodontist <p>XII. The following are considered investigational:</p> <ul style="list-style-type: none"> A. Nasal expiratory positive airway pressure B. Oral pressure therapy devices C. Mandibular/palatal expansion devices for the treatment of OSA D. The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) E. The use of a sleep positioning trainer with vibration F. The use of daytime electrical stimulation of the tongue G. The use of CPAP, bi-level positive airway pressure, APAP, ASV and intraoral appliances that do not meet the above criteria for the treatment of OSA H. Unattended home sleep apnea test for a child (younger than 18 years of age) I. Multiple sleep latency testing (MSLT) in the initial workup (diagnosis) of OSA |

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| | J. Mandibular repositioning (daytime), bruxism and anti-snoring oral appliances for the treatment of OSA |