

Corporate Medical Policy

Sleep Apnea: Diagnosis and Medical Management

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Description of Procedure or Service

Sleep apnea is a disorder where breathing nearly or completely stops for periods of time during sleep. Sleep apnea may be further classified into three categories, obstructive sleep apnea (OSA), central sleep apnea (CSA) and complex sleep apnea (CompSA). Obstructive sleep apnea is the most common category of sleep apnea. In obstructive sleep apnea, the brain sends the message to breathe, but there is a blockage to air flowing into the chest. It is a condition in which repetitive episodes of upper airway obstruction occur during sleep. The obstruction may be localized to one or two areas, or may encompass the entire upper airway passages to include the nasal cavity (nose), oropharynx (palate, tonsils, tonsillar pillars) and hypopharynx (tongue base). The hallmark clinical symptom of OSA is excessive daytime sleepiness.

Upper airway resistance syndrome (UARS) is a variant of OSA and is characterized by a partial collapse of the airway resulting in increased resistance to airflow without apnea or hypopnea. This causes many short episodes of breathing difficulties to occur each night, leading to brief arousals and sleep fragmentation. The patient does not actually stop breathing during sleep. The disruption in sleep can cause excessive daytime sleepiness.

In central sleep apnea, the message that is normally sent from the brain to the chest muscles to initiate breathing does not reliably occur during sleep. Patients with CSA show no signs of attempts to breathe despite an open airway. CSA is common in patients with heart failure, after stroke or brain injury. There are several types of central sleep apnea, including high altitude-induced periodic breathing, idiopathic CSA, narcotic-induced central apnea, obesity hypoventilation syndrome, and Cheyne-Stokes breathing.

Complex sleep apnea is a combination of both obstructive and central sleep apneas. Patients with CompSA at first appear to have OSA but unlike typical OSA patients, central apneas persist or emerge during treatment attempts with a continuous positive airway pressure (CPAP) or bilevel device.

Consequences of sleep apnea may include excessive daytime sleepiness, hypertension, cardiac arrhythmias, pulmonary hypertension, and stroke. Excessive daytime sleepiness is a result of fragmented sleep due to repeated arousals during sleep which can lead to impairment of almost any daytime activity.

OSA is often suspected on the basis of the clinical history, patient symptoms and physical exam. Excessive daytime sleepiness is predominantly a subjective symptom. The Epworth Sleepiness scale is a popular, quick, and easy self-administered questionnaire that asks patients their likelihood of falling asleep in 8 situations ranked from 0 (would never doze) to 3 (high chance of dozing). The numbers are then added together to give a global score between 0 and 24. A value of 10 or below is considered normal. The 8 situations are as follows:

1. Sitting and reading
2. Watching TV

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3. Sitting inactive in a public place, i.e., theater
4. As a passenger in a car for 1 hour without a break
5. Lying down to rest in the afternoon when circumstances permit
6. Sitting and talking with someone
7. Sitting quietly after lunch without alcohol
8. In a car, while stopped for a few minutes in traffic

The criterion standard diagnostic test for sleep apnea is considered a polysomnogram performed in a sleep laboratory. Polysomnography consists of monitoring and recording physiologic data during sleep. A standard polysomnogram, supervised by a sleep lab technician, typically includes:

- EEG [electroencephalography] (to stage sleep, detect arousal)
- Submental electromyogram
- Electro-oculogram (to detect arousal, rapid eye movement [REM] sleep)

Additional parameters of sleep that may be measured include:

- Respiratory airflow and effort (to detect apnea)
- Oxygen desaturation
- Electrocardiography
- Sleep position
- Leg movement
- Chest and abdominal excursions
- Continuous blood pressure monitoring
- Snoring

The first 3 elements listed here (EEG, submental electromyogram, and electro-oculogram) are required for sleep staging. By definition, a polysomnogram always includes sleep staging, while a cardiorespiratory "sleep study" does not. The actual components of the study will be dictated by the clinical situation. Supervision of the test may be considered important to ensure that the monitors are attached appropriately to the patient and do not become dislodged during the night. In addition, an attendant can identify severe OSA so that the effective level of continuous positive airway pressure (CPAP) therapy can be determined. These studies are known as "split-night" studies, in which the diagnosis of OSA is established during the first half of the night and CPAP titration is conducted during the second half of the night. If successful, this strategy can eliminate the need for an additional polysomnogram for CPAP titration.

Typically, the evaluation of obstructive sleep apnea includes sleep staging to assess arousals from sleep, and determination of the frequency of apneas and hypopneas from channels measuring oxygen desaturation, respiratory airflow, and respiratory effort. An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. Obstructive hypopnea is a reduction, but not a cessation of air exchange, with an associated fall in oxygen saturation (at least 3%–4%) or arousal. The apnea/ hypopnea index (AHI) may also be referred to as the respiratory disturbance index (RDI). The AHI is defined as the total number of events per hour of sleep. When sleep onset and offset are unknown, the RDI may be calculated based on the total recording time. A diagnosis of OSA syndrome is accepted when an adult patient has an AHI >5 and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI greater than or equal to 15 is typically considered moderate OSA, while an AHI greater than 30 is considered severe OSA. Although there is poor correlation between AHI and OSA symptoms, an increase in mortality is associated with an AHI of greater than 15. Mortality has not been shown to be increased in patients with an AHI between 5 (considered normal) and 15. Diagnosis of UARS rests on polysomnographic documentation of >10 EEG arousals per hour of sleep correlated with episodes of reduced intrathoracic pressure. Sources of

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measurement error with polysomnography include data loss, artifact, event recognition errors, measurement errors, use of different types of leads, and night-to-night variability.

It is estimated that about 7% of adults have moderate or severe OSA and 20% have at least mild OSA, and that the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease. In light of the limited capacity of sleep laboratories, a variety of devices have been developed specifically to evaluate OSA at home. These 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 the majority of portable monitors do not record EEG. It has been proposed that unattended studies with portable monitoring devices may improve the diagnosis and treatment of patients with OSA, although the limited number of channels in comparison with full polysomnographic recording may decrease the capability for differential diagnosis or detection of comorbid conditions.

Medical management of OSA includes lifestyle modification (weight loss, avoidance of alcohol, sedatives and caffeine consumption, especially before bedtime, allowing adequate sleep time, maintenance of appropriate body position during sleep [side versus back]), oral appliances and positive airway pressure devices (CPAP [continuous positive airway pressure], BiPAP [bilevel positive airway pressure], and APAP [automatic positive airway pressure]). (see policy titled Noninvasive Respiratory Assist Devices.) On average, a 10% weight loss produces an improvement of 50% in the apnea-hypopnea index. Oral appliances act by holding the mandible and tongue forward during sleep. The use of atrial overdrive pacing is also being evaluated in the treatment of OSA. This approach is being tried because of the bradycardia that generally occurs during episodes of apnea.

EPAP can also be used to describe a device used to treat sleep apnea called Provent® (Ventus Medical). According to the manufacturer, Provent® uses a one-way valve that is placed over the nostrils at nighttime. The valve opens with inhalation, but partially closes during exhalation, creating positive pressure in the airway.

The Winx™ Sleep Therapy System (ApniCure™, Redwood City, CA) is a single pressure, oral airway device that operates without a mask or forced nasal air. Oral pressure therapy (OPT) 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.

Oral appliances can be broadly categorized as mandibular advancing/positioning devices or tongue retaining devices. Oral appliances can either be “off the shelf” or custom made for the patient by a dental laboratory or similar provider. A number of oral appliances have received marketing clearance through the 510(k) pathway for the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™, Lamberg SleepWell-Smartrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, Desra, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device.

The Daytime Nighttime Appliance (DNA Appliance, Biomodeling Solutions) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance, Biomodeling Solutions) are customized palate and mandible expanding devices. In addition to the upper-jaw device that is common to both the DNA Appliance and the rRNA 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 expand the upper and lower jaw and airway gradually to treat and eliminate mild-to-moderate OSA eventually.

Related Policy

Surgery for Obstructive Sleep Apnea and Upper Airway Resistance Syndrome

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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Policy

BCBSNC will provide coverage for Diagnosis and Medical Management of Sleep Apnea when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

CPAP is covered under DME benefits. Please refer to Certificate for availability of benefits and any prior review requirements regarding the rental/purchase of equipment. See Covered Services, Durable Medical Equipment. Also, refer to policy, "Durable Medical Equipment (DME)" for information re: rental/purchase.

DME Supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.

Refer to policy, "Noninvasive Respiratory Assist Devices" for treatment with devices other than CPAP.

When Diagnosis and Medical Management of Sleep Apnea is covered

I) Diagnosis of Sleep Apnea:

- A) Sleep testing must be performed in a sleep laboratory either affiliated with a hospital or under the direction and control of physicians, with trained medical professionals present whenever testing is performed. For the purposes of this policy, an attended (or supervised) study requires the constant presence of a trained individual who can monitor for technical adequacy, patient compliance, and relevant patient behavior.
- B) Supervised polysomnography performed in a sleep laboratory may be considered medically necessary as a diagnostic test in patients with any of the following (1, 2, or 3):
 - 1) Observed apneas during sleep; OR
 - 2) A combination of at least two of the following (a - e):
 - (a) Excessive daytime sleepiness evidenced by an Epworth Sleepiness Scale greater than 10, inappropriate daytime napping (e.g., during driving, conversation, or eating), or sleepiness that interferes with daily activities and is not explained by other conditions;
 - (b) Habitual snoring, or gasping/choking episodes associated with awakenings;
 - (c) Unexplained hypertension;
 - (d) A body mass index greater than 35 kg/m²;
 - (e) Craniofacial or upper airway soft tissue abnormalities; OR
 - 3) Moderate or severe congestive heart failure, stroke/transient ischemic attack, coronary artery disease, or significant tachycardia or bradycardic arrhythmias in patients who have nocturnal symptoms suggestive of a sleep-related breathing disorder or otherwise are suspected of having sleep apnea.
- C) A supervised polysomnogram must include, at a minimum, measurement of all of the following:
 - 1) Electroencephalography (EEG),
 - 2) Electro-oculography (EOG),
 - 3) Submental (or chin) electromyography (EMG),
 - 4) Extremity muscle activity,
 - 5) Respiratory effort,

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- 6) Airflow,
 - 7) Arterial oxygen saturation,
 - 8) Electrocardiography (ECG) or heart rate.
- D) A single unattended (unsupervised) home sleep study with a minimum of 4 recording channels (including oxygen saturation, respiratory movement, airflow, and EKG or heart rate) may be considered medically necessary in adult patients who are at high risk for obstructive sleep apnea (OSA) as described in the Policy Guidelines and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including the following:
- 1) central sleep apnea
 - 2) congestive heart failure
 - 3) chronic pulmonary disease
 - 4) obesity hypoventilation syndrome
 - 5) narcolepsy
 - 6) injurious or potentially injurious parasomnias
- E) A single unattended (unsupervised) home sleep study with a minimum of 4 recording channels (see above) may be considered medically necessary as a screening tool in patients who are scheduled for bariatric surgery and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment.
- F) Auto-adjusting positive airway pressure (APAP) may be considered medically necessary for the titration of pressure in adult patients with clinically significant OSA defined as those patients who have:
- An Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of at least 15 per hour; or
 - An AHI or RDI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

Repeated unattended (unsupervised) home sleep studies with a minimum of four recording channels (including oxygen saturation, respiratory movement, airflow, and EKG/heart rate) may be considered **medically necessary** in adult patients under the following circumstances:

- 1) To assess efficacy of surgery or oral appliances/devices; OR
 - 2) To re-evaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued.
- G) Criteria required of the physician who interprets and bills the unattended sleep studies (HST-Type II, III, or IV) must include at least one of the following:
- 1) Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM), OR
 - 2) Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS), OR
 - 3) Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible, OR
 - 4) Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or The Joint Commission (Formerly the Joint Commission on Accreditation of Healthcare).

II) Medical Management of Sleep Apnea:

- A) Medical therapy, when appropriate to the clinical situation, includes: weight loss, avoidance of alcohol, sedatives and caffeine consumption, especially before bedtime, allowing adequate sleep time, maintenance of appropriate body position during sleep (side versus back), oral

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appliances, positive airway pressure devices and a medically supervised smoking cessation program.

- B) Removable intraoral appliances (mandibular advancing/positioning devices, tongue-retaining devices) may be indicated for use in patients with clinically significant OSA under the following conditions:
- Mild to moderate OSA, defined in adults by:
 - AHI greater than or equal to 15 but less than 30; **OR**
 - AHI greater than or equal to 5 but less than 15, **with any** of the following associated symptoms which are documented by medical records:
 - (i) Excessive daytime sleepiness (as evidence by a pre-treatment Epworth score of greater than 10); or
 - (ii) Impaired cognition; or
 - (iii) Mood disorders; or
 - (iv) Insomnia; or
 - (v) Hypertension; or
 - (vi) Ischemic heart disease; or
 - (vii) History of stroke; **OR**
 - For severe OSA (AHI greater than or equal to 30 in adults), a trial of CPAP was not tolerated at the time of a full or split-night titration study, has failed, or is contraindicated, **AND**
 - Diagnosis of OSA, whether by attended or unattended study, meets the testing and provider qualification criteria under “When Diagnosis and Medical Management of Sleep Apnea is covered”, **AND**
 - The device is prescribed by a treating physician, **AND**
 - The device is custom-fitted by qualified dental personnel.

Please see “Policy Guidelines” section of this policy regarding diagnosis of mild to moderate, and severe obstructive sleep apnea in children.

- C) CPAP may be considered medically necessary in patients with clinically significant OSA documented by supervised polysomnography or an unattended (unsupervised) home sleep study with a minimum of four recording channels (including oxygen saturation, respiratory movement, and airflow) and defined as **those** patients who meet **1 or 2** below. Prior to initiation of CPAP, conservative medical therapy as indicated in A) above must be considered and applied as appropriate to the clinical situation.
- 1) An AHI \geq 15; **OR**
 - 2) An AHI greater than or equal to 5 but less than 15 **with any** of the following associated symptoms which must be documented by medical records:
 - (a) Excessive daytime sleepiness (as evidence by a pre-testing Epworth score of greater than 10); or
 - (b) Impaired cognition; or
 - (c) Mood disorders; or
 - (d) Insomnia; or
 - (e) Documented hypertension; or
 - (f) Ischemic heart disease; or
 - (g) History of stroke.
- *The patient selection criteria in C.1) and 2) were adopted from the Medicare policy for coverage of CPAP. The presence of conditions in C.2) a-g above must be documented in the medical record and must be of clinical significance.
- D) Auto-adjusting positive airway pressure (APAP) may be considered medically necessary during a 2-week trial to initiate and titrate CPAP in adult patients with clinically significant obstructive sleep apnea.
- E) CPAP may be considered medically necessary in patients with central sleep apnea documented by supervised polysomnography.

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- F) CPAP may be considered medically necessary in patients with complex sleep apnea documented by supervised polysomnography.

Note: A split-night study, in which sleep apnea is documented during the first portion of the polysomnogram followed by CPAP titration during the second portion, may eliminate the need for a second study to titrate CPAP. The Plan expects a split-night study to be performed when the AHI is greater than 20 after the first 2-3 hours. On occasion, an additional full-night CPAP titration may be necessary if the split-night study did not allow for the abolishment of the vast majority of respiratory events or prescribed CPAP treatment does not control clinical symptoms.

- G) Adherence to and failure of CPAP Treatment: A good faith effort at CPAP compliance must be documented in the medical record and includes the following:
- 1) CPAP must be prescribed based on a CPAP titration to obtain the most effective pressure compatible with patient comfort.
 - 2) The CPAP DME supplier and the sleep specialist must undertake appropriate measures to maximize the chance of success with CPAP. Measures to acclimate members to therapy may include, but are not limited to, one or more of the following:
 - (a) Emotional support to overcome initial reluctance where appropriate, with specific attention to addressing mask intolerance due to anxiety. Mask intolerance must be addressed by the sleep specialist prior to being accepted as a reason for failure of CPAP.
 - (b) Alternate mask fitting for effect and comfort.
 - (c) Nasal pillows.
 - (d) Ramping (which allows for a gradual increase in pressure).
 - (e) Humidification.

In patients who are unable to complete a satisfactory CPAP titration because of mask intolerance due to anxiety, unfamiliarity, or other non-physical reasons, a separate, dedicated, in-lab titration may be successful if the initial titration was time-limited due to its being part of a split-night study. If one or more titration efforts are unsuccessful, a one-month trial of home acclimation with autotitrating CPAP including gradual, daytime, non-sleeping exposure to the use of the system with documented follow-up and results must be provided.

Acclimation efforts, when necessary, should be attempted for a minimum of two months, and must be supported by proper documentation and compliance chip information before CPAP therapy will be considered a failure. Multiple visits to the sleep specialist during the acclimation period are expected, with documentation of all above efforts as applicable. Documentation must include ongoing management by the sleep specialist of two months or greater.

Prior to coverage of alternative noninvasive respiratory assist devices or surgery, adequate adherence to CPAP, defined as an average of 4.5 hours of CPAP use per night on a routine basis, must be demonstrated unless the above efforts at acclimation have been documented as adequately tried and failed.

Refer to policy, "Noninvasive Respiratory Assist Devices", for treatment with devices other than CPAP.

When Diagnosis and Medical Management of Sleep Apnea is not covered

I) Diagnosis of Sleep Apnea:

- A) Diagnostic sleep testing for the following conditions is not medically necessary. They can be diagnosed through more appropriate means.
- 1) Bruxism
 - 2) Drug dependency
 - 3) Enuresis
 - 4) Insomnia
 - 5) Night terrors or dream anxiety attacks

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- 6) Nocturnal myoclonus
 - 7) Restless leg syndrome
 - 8) Shift work and schedule disturbances
 - 9) Somnambulism
 - 10) Migraine Headaches
 - 11) Snoring without other signs/symptoms of OSA
- B) Unattended (unsupervised) sleep studies are considered investigational in patients who are considered at low to moderate risk for OSA.
 - C) Unattended sleep studies utilizing fewer than 4 channels are considered investigational for the diagnosis of sleep apnea syndromes.
 - D) Unattended sleep studies for the diagnosis of complex sleep apnea are considered investigational.
 - E) Unattended home sleep studies are considered investigational in children (younger than 18 years of age)
 - F) Electrosleep therapy, which uses the passage of weak electric currents to the brain to induce sleep, is considered investigational.
 - G) Topographic electroencephalogram (EEG) mapping is considered investigational in the diagnosis and/ or medical management of obstructive sleep apnea syndrome.
 - H) Multiple sleep latency testing (MSLT) is considered not medically necessary in the diagnosis of obstructive sleep apnea syndrome, except to exclude or confirm narcolepsy.
 - I) Actigraphy (including but not limited to the Watch-PAT device) is a method used to study sleep-wake patterns and circadian rhythms by assessing body movement. Actigraphy devices are typically placed on the wrist, ankle, or trunk to record movement. Data are collected and downloaded to a computer for display and analysis. Actigraphy is considered investigational as a technique to record and analyze body movement, including but not limited to its use to evaluate sleep disorders.
 - J) Video recording during polysomnography for the diagnosis of OSA in children or adults is considered part of the standard polysomnography test and is not separately reimbursable.
 - K) Multiple consecutive nights of supervised or unattended (unsupervised) sleep studies that do not meet the above criteria for repeat studies are not medically necessary.
 - L) The use of an abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies is considered investigational.

II) Medical Management of Sleep Apnea:

- A) Over the counter bite guards are not covered.
- B) CPAP is not covered when the above medical criteria and guidelines are not met.
- C) Treatment of snoring without significant OSA is considered not medically necessary.
- D) Atrial pacing is considered investigational in the treatment of OSA.
- E) A nasal expiratory positive airway pressure (EPAP) device is considered investigational in the treatment of OSA.
- F) Single pressure, oral airway devices without forced nasal air are not considered CPAP and are considered investigational in the treatment of OSA.
- G) Palate and mandible expansion devices are considered investigational for the treatment of OSA.

Policy Guidelines

The medical professional who is requesting, performing, and evaluating a polysomnogram or home sleep study should have training in sleep medicine, and should have performed a face to face evaluation of the patient. In addition, the treatment of patients diagnosed with OSA should be initiated and monitored by a professional with training in sleep medicine.

Although not an exclusive list, patients with all 4 of the following symptoms are considered to be at high risk for OSA:

- habitual snoring;
- observed apneas;

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- excessive daytime sleepiness;
- a body mass index greater than 35

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, or craniofacial or upper airway soft tissue abnormalities) may be considered. Objective clinical prediction rules are being developed, however, at the present time risk assessment is based on clinical judgment.

In the current (2005) practice parameters of the American Academy of Sleep Medicine, there are 4 types of monitoring procedures: type 1, standard attended in-lab comprehensive polysomnography; type 2, comprehensive portable polysomnography; 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 polysomnography are often used interchangeably. Polysomnography 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.

Cardiorespiratory sleep studies without EEG may be called polygraphic studies, and can either be attended or unattended by a technologist. A wide variety of portable monitors and proprietary automated scoring systems are being tested and marketed, but the optimum combination of sensors and scoring algorithms is currently unknown. Current recommendations are that the portable monitoring device have at least 3 channels (e.g., oxygen saturation, respiration, and heart rate), and allow review of the raw data. Type IV monitors with less than 3 channels are not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional with training in sleep medicine in order to detect artifacts and data loss.

CPAP claims will be handled as follows:

1. CPAP equipment will be rented with rental fees applied to purchase price for a minimum trial period of three months to document patient compliance, patient tolerance, and clinical benefits prior to purchase.
2. Payment for CPAP includes payments for the provision of all necessary accessories, i.e., mask, tubing, or cannula. Separate charges for replacement of masks, tubing, cannula or for respiratory equipment maintenance services are not covered since they are included in the rental payment for CPAP.

The American Academy of Sleep Medicine has issued guidelines concerning the use of oral appliances (OA) in the treatment of OSA.

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

Use of the novel EPAP device has been reported in several prospective case series and one industry-sponsored randomized controlled trial. The main finding of this study was a decrease in AHI with minor impact on oxygenation and the Epworth Sleepiness Scale. No evidence was identified on the oral pressure therapy device. Evidence at this time is insufficient to permit conclusions regarding the effect of these technologies on health outcomes. One comparative trial with historical controls was identified on use of a PAP-NAP study for patients with complex insomnia who are resistant to CPAP titration or use. Additional study is needed to evaluate the efficacy of this intervention with greater certainty.

Obstructive Sleep Apnea in Children

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OSA is also common in children, but differs somewhat from the presentation in adults (i.e., excessive daytime sleepiness, the cardinal symptom in adults is rare in young children). The prevalence of pediatric sleep apnea is estimated to be between 1-3% of children with a peak age of two to five years. Night time symptoms of OSA in children include habitual snoring (often with intermittent pauses, snorts, gasps or choking sounds), abnormal motor activity, heavy sweating, bed wetting at an inappropriate age, sleeping in abnormal positions such as with neck hyperextended, arousal from sleep, nightmares. Daytime symptoms caused by the disruption of normal sleep may include morning headache, behavior disturbances, poor school performance and excessive daytime sleepiness (typical in older children or adolescents, but not younger children).

Indications for pediatric polysomnography where obstructive sleep apnea syndrome is suspected:

- To differentiate benign or primary snoring from pathological snoring; **or**
- To evaluate disturbed sleep patterns, excessive daytime sleepiness, cor pulmonale, failure to thrive or polycythemia unexplained by other factors or conditions, especially if the child also snores; or
- Observation of increased respiratory efforts, labored breathing, or sternal or intercostal retractions during sleep; or
- Witnessed apnea greater than 2 respiratory cycle times (inspiration and expiration); or
- Hypertrophy of tonsils and adenoids associated with noisy daytime respirations where surgical removal poses a significant risk and would be avoided in the absence of sleep disordered breathing.

An apnea/hypopnea index (AHI) >1.5 is considered abnormal (mild to moderate obstructive sleep apnea; an AHI of 15 or greater is considered severe). The first-line treatment in children is usually adenotonsillectomy.

CPAP and oral appliances may be considered medically necessary for the treatment of clinically significant OSA in children.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 94660, 95782, 95783, 95800, 95801, 95803, 95805, 95806, 95807, 95808, 95810, 95811, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046, A7047, E0485, E0486, E0561, E0562, E0601, G0398, G0399, G0400, S8040

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

For Policy entitled: Medical Management of Obstructive Sleep Apnea

BCBSA Medical Policy Reference Manual - 11/96

Medical Policy Advisory Group - 12/99

For Policy entitled: Sleep Disorders Clinics

TEC Bulletin - 5/24/96

Medical Policy Advisory Group - 3/99

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For Policy entitled: Nasal Continuous Positive Airway Pressure

Medicare Region C DMERC Supplier Manual (9/93)

Medicare Coverage Manual 60-17

Senior Director, Medical Affairs - 12/94

Vice President, Medical Affairs (DPAP) - 8/95

Consultant Review (DPAP) - 8/95

BCBSA Medical Policy Reference Manual 11/96

Medical Policy Advisor Group - 12/99

For new Policy entitled: Sleep Apnea and Breathing Related Sleep Disorders

Evidence Report/Technology Assessment No. 1, Systematic Review of the Literature Regarding the diagnosis of Sleep Apnea (AHCPR Publication No. 99-E002).

Ferber R, Millman R, Coppola M, et al. ASDA Standards of Practice. Portable Recording in the Assessment of Obstructive Sleep Apnea. *Sleep*. 1994;17:378-392.

Thorpy M, Chesson A, Ferber R, et al. Practice Parameters for the Use of Portable Recording in the Assessment of Obstructive Sleep Apnea. *Sleep*. 1994;17(4):372-377.

Laser-Assisted Uvulopalatoplasty for the Treatment of Simple (Nonapneic) Snoring and Obstructive Sleep Apnea. ECRI. March 1995.

Indications for Polysomnography Task Force. American Sleep Disorders Association Standards of Practice Committee. Practice Parameters for the Indications for Polysomnography and Related Procedures. *Sleep*. 1997;20(6):406-422.

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Policy Implementation/Update Information

For Policy entitled: Medical Management of Obstructive Sleep Apnea

4/97 New policy developed. Medical and Surgical Policies separated.

9/99 Reformatted, Medical Term Definitions added.

12/99 Medical Policy Advisory Group

For Policy entitled: Sleep Disorders Clinics

7/82 Original Policy

6/84 Reaffirmed

7/96 Revised: Portable sleep studies for diagnosis of obstructive sleep apnea is investigational.

3/99 Medical Policy Advisory Group - Reaffirmed

7/99 Reformatted, Medical Term Definitions added.

For Policy entitled: Nasal Continuous Positive Airway Pressure

12/94 Original Policy issued

8/95 Revised: Added DPAP to policy

1/97 Reaffirmed: Combined Local and National Policies

8/97 Reviewed: Added under Policy Guidelines requirement to rent for a period of six months prior to purchase

2/98 Reviewed: Added information in the Benefit Application section.

9/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.

12/99 Medical Policy Advisory Group

New Policy formed entitled: Sleep Apnea and Breathing Related Sleep Disorders

10/00 New Policy issued. Specialty Matched Consultant review. Medical Policy Advisory Group review. Coding revised in billing/coding sections. System coding changes.

10/01 Coding format changes.

11/01 Removed references to automobile accidents related to narcolepsy.

01/02 CPT code 41120 added to the Billing and Coding section of the policy. This code is not covered when used to bill a somnoplasty.

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- 06/02 Reformatted When Treatment of Sleep Apnea and Breathing Related Sleep Disorders are covered section for understanding. Changed When Treatment of Sleep Apnea and Breathing Related Sleep Disorders section to indicate that Somnoplasty is a Trade Mark which refers to radiofrequency tissue volume reduction (Somnoplasty™). The following codes were removed from the policy: DM495, E0452, K0269. The following codes were added to the policy: 30520, 42825, 42826, 99508, K0268, K0531, K0532, K0533, K0534.
- 07/02 Specialty Matched Consultant Review 6/2002. Removed references regarding patients with an RDI >30 not being candidates for UPPP.
- 10/02 Changed date of next review.
- 10/14/04 Specialty Matched Consultant Advisory Panel review - 6/21/04. Multiple updates and clarifications. Under Section I - "When not Covered" - B. Unattended (unsupervised) sleep studies are considered investigational. Under Section II - "When Covered" - A. Medical Management, good faith effort at CPAP compliance added; B. Surgical Management, clinically significant UARS included; "When not Covered" - C. Additional non-covered surgical procedures listed, including RFVTR (Somnoplasty) of nasal turbinates, the Repose System, injection snoreplasty, CAPSO. Section I - "Billing/Coding" - removed deleted CPT code 99508. Section II - "Billing/Coding" - added the following HCPCS codes: A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, E0470, E0471, E0472, E0561, E0562, S2080; Removed CPT codes 42825, 42826; Removed the following deleted HCPCS codes: K0183-K0189, K0268, K0531, K0532, K0533, K0534. Sources added. Notification given 10/14/04. Effective date 12/23/04.
- 12/23/04 Added 2005 CPT code 0088T to Billing/Coding section for Treatment of Sleep Apnea and Breathing Related Sleep Disorders in Adults and to final Billing/Coding section that includes all codes in policy.
- 1/20/05 Specified "in Adults" to name of policy with 10/14/04 notice and effective date of 12/23/04. This was inadvertently omitted from 10/14/04 information.
- 05/19/05 Added CPT code 21685 to Billing/Coding section for Treatment of Sleep Apnea and Breathing Related Sleep Disorders in Adults and to final Billing/Coding section that includes all codes in policy.
- 6/16/05 Section II: "When treatment of sleep apnea and breathing related sleep disorders is not covered"; C.4 now reads "Palatal stiffening procedures, including but not limited to, cautery-assisted palatal stiffening operation (CAPSO), **and the implantation of palatal implants**, are considered not medically necessary in the treatment of snoring alone, and are considered investigational as a treatment for UARS or OSA." Under same section removed C.7 "Cautery-Assisted palatal stiffening operation (CAPSO) is considered investigational." since it is now included in C.4 above; previous items C.4, 5 and 6 were renumbered to 5, 6, and 7 due to the changes. Reference source and key words added.
- 9/1/05 Section II.B.2 - added "e. tonsillectomy". CPT code 42826 added to Billing/Coding section.
- 1/19/06 Added codes E0485 & E0486 to appropriate Billing/Coding sections.
- 6/4/07 **Description** section: Last two paragraphs revised.
- Section I-Diagnostic Sleep Testing in Adults, When Not Covered: Deleted A.4.** "Hypersomnia without other signs/symptoms of OSA"; **added F.** "Actigraphy is a method used to study sleep-wake patterns and circadian rhythms by assessing body movement. Actigraphy devices are typically placed on the wrist, ankle, or trunk to record movement. Data are collected and downloaded to a computer for display and analysis. Actigraphy is considered investigational as a technique to record and analyze body movement, including but not limited to its use to evaluate sleep disorders."

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Section I-Diagnostic Sleep Testing in Adults, Policy Guidelines: Third sentence of first bullet revised and made a separate bullet: "A follow-up supervised polysomnogram may be indicated for the assessment of treatment results in the following circumstances: after surgical treatment (i.e., Uvulopalatopharyngoplasty [UPPP]), after substantial weight gain or weight loss, or change in symptoms suggesting that CPAP should be retitrated or discontinued." Last sentence of first bullet made third bullet ("More than three polysomnograms..."). "Medically necessary services rendered..." is now fourth bullet.

Section II-Treatment of Sleep Apnea and Breathing Related Sleep Disorders in Adults, When Covered: **A.1.** deleted >5 and inserted "greater than 10 and less than 30 (mild to moderate sleep apnea)" **A.3.** Added underlined wording "These measures to acclimate members to therapy include emotional support to overcome initial reluctance where appropriate, *with specific attention to addressing claustrophobia.*" At **end of A.3.** added "Documentation must include ongoing management by sleep specialist of 3 months or greater. Claustrophobia must be addressed by sleep specialist prior to being accepted as a reason for failure of CPAP. **B. Surgical Management:** revised "Conservative measures *as appropriate for an individual clinical situation* must have been tried and failed prior to considering surgical management (see Policy Guidelines below). Preoperative evaluation ~~must~~ ~~should~~ include a comprehensive *sleep* history with a complete head and neck examination, including a visual examination of the hypopharynx and larynx. A complete head and neck examination for OSA *may* include, *as adjunctive measures*, a flexible fiberoptic examination, Müller maneuver and/or cephalometrics as needed in order to determine the site of obstruction as nearly as clinically possible. **B.1.b.** corrected per minute to per *hour*. **B.2.a.** revised: "Uvulopalatopharyngoplasty (UPPP) may be considered medically necessary for the treatment of clinically significant OSA or clinically significant UARS *if performed to enhance CPAP or BiPAP effectiveness* in patients who have tried and failed a good faith effort at treatment with CPAP, BiPAP or DPAP and whose physical examination evidences obstruction at the palatal level." **B.2.b.** revised: "Hyoid suspension, surgical modification of the tongue (including genioglossus advancement), and/or maxillofacial surgery, including mandibular-maxillary advancement (MMA), may be considered medically necessary in patients with clinically significant OSA and objective documentation of hypopharyngeal obstruction by physical examination *if performed to enhance CPAP or BiPAP effectiveness*, who have tried and failed a good faith effort at treatment with CPAP, BiPAP or DPAP. Orthognathic surgery will not be approved as the first surgical therapy for OSA unless otolaryngology evaluation has ruled out obstruction at a higher anatomic level (i.e., nose, palate). **B.2.c.** Revised to "Septoplasty when *patient has OSA with a documented AHI greater than 5, and septoplasty is being performed.....*" Added **B.2.f.** turbinate surgery.

Section II-Treatment of Sleep Apnea and Breathing Related Sleep Disorders in Adults, When Not Covered: **C.2.** revised: "Laser-assisted uvulopalatoplasty (LAUP) ~~or~~ ~~and~~ radiofrequency volumetric tissue reduction (Somnoplasty™) ~~are~~ ~~is~~ considered not medically necessary in the treatment of snoring alone and ~~are~~ ~~is~~ considered investigational ~~and not effective~~ as a treatment of UARS or OSA. **C.3.** Revised to include C.8: "Radiofrequency volumetric tissue reduction (RFVTR, Somnoplasty) of nasal turbinates is considered not medically necessary for snoring ~~and is considered investigational for treatment of OSA.~~" **C.4.** Clarified palatal implants: "Palatal stiffening procedures, including but not limited to, cautery-assisted palatal stiffening operation (CAPSO), and the implantation of palatal implants (*e.g., the "Pillar Procedure"*) are considered not medically necessary in the treatment of snoring alone, and are considered investigational as a treatment for UARS or OSA." **C.5.** revised "Radiofrequency volumetric tissue reduction of the ~~soft palate~~, uvula and/or tongue base (Somnoplasty™) or the nasal passages and soft palate (Coblation) is considered investigational *for treatment of OSA.*" **Deleted C.8.** since it is now included in C3. "Note:" re: simple snoring moved to the end of section and revised: "Because snoring, in the absence of documented obstructive sleep apnea, is not an illness or a disease, treatment of snoring, including **any** surgical intervention is considered not medically necessary and therefore is not covered. Snoring does not fall within the

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definition of medical necessity. (Refer to separate policy number MED1301, Medical Necessity.)"

Section II-Treatment of Sleep Apnea and Breathing Related Sleep Disorders in Adults, Policy Guidelines: Rather than bullets, each entry is now numbered. **Second main bullet, now #2**="Conservative measures ~~should~~ *must* have been tried and failed prior to considering surgical management. Conservative *medical therapy, when appropriate to the clinical situation, may include* weight loss, avoidance of alcohol, sedatives and caffeine consumption, especially before bedtime, allowing adequate sleep time, body position during sleep (side versus back), oral appliances, ~~and~~ positive airway pressure devices *and medically supervised smoking cessation program.*" **Added #3** "The Plan recognizes and affirms that positive airway pressure (e.g., CPAP, BiPAP) is the treatment of choice for obstructive sleep apnea. For this reason the general rule is that a good faith effort at positive pressure must be tried and failed prior to coverage of surgical treatment." Moved and revised last sentence of second main bullet, **now #4.** "Surgery is to be reserved for patients who have not responded to *appropriate* medical alternatives." **Added #5** "For any request for approval of a surgical procedure, current polysomnogram data (including the initial sleep study, any CPAP titration data, and any other studies such as MSLT that have been performed) must be submitted for review with the supporting medical record documentation. Generally, the sleep study upon which approval is requested must be less than 18 months old." **Added #6** "Polysomnography data should include the entire sleep study record, as opposed to merely a summary. The following information must be available in the study report: Total sleep time for the study; Total RDI or AHI for the study; Average and lowest recorded oxygen saturation; For any desaturations below 90%, the length of time at the abnormally low saturation level or range; Obstructive event indices for supine and non-supine positions, along with total sleep time spent supine; Periodic leg movement (PLM) index; For CPAP titrations: optimum pressure, event index at that pressure, and total sleep time on CPAP. *The Plan may require the complete polysomnogram data at its discretion. **Added #7** "A polysomnogram that does not distinguish between supine and non-supine obstructive events, to the extent that any possible positional predisposition to obstruction can be determined, is not complete and may not be sufficient to support a surgical request.". **Added #8** "The Plan may require a repeat polysomnogram to support a request for additional surgical therapy after prior surgical therapy based on the initial polysomnogram.";

Medical Term Definitions: Added definition of Upper Airway Resistance Syndrome.

Billing/Coding sections: Added CPT codes 21199, 30130, 30140, 30801, 30802 and 0089T.

Scientific Background and Reference Sources: Reference sources added. (pmo)

- 7/2/07 HCPCS codes K0553, K0554 and K0555, effective July 1, 2007, added to appropriate Billing/Coding section. (pmo)
- 1/14/08 Under "Billing/Coding" section removed deleted HCPCS codes K0553, K0554 and K0555 and added the codes that replaced them - A7027, A7028 and A7029. (pmo)
- 01/05/09 Under appropriate "Billing/Coding" sections, removed CPT codes 0088T and 0089T and added the codes that replaced them - 41530 and 95803. Also added CPT codes 41500 and 41512. Code additions and deletions to be effective January 1, 2009. (pmo)

For New Policy entitled: Sleep Apnea: Diagnosis and Medical Management

- 12/21/09 Notification of new policy entitled Sleep Apnea: Diagnosis and Medical Management. **THIS POLICY IS NOT EFFECTIVE UNTIL MARCH 30, 2010.** Prior to March 30, 2010 refer to policy number OTH8138, Sleep Apnea and Breathing Related Sleep Disorders in Adults. The policy entitled Sleep Apnea and Breathing Related Sleep Disorders in Adults

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- has been separated into three policies and will be archived on March 30, 2010. Notification given December 21, 2009. Effective date March 30, 2010. (pmo)
- 3/30/2010 Under "Billing/Coding" section, added codes 0203T and 0204T.
- 6/22/10 Policy Number(s) removed (amw)
- 7/20/10 Specialty Matched Consultant Advisory Panel Review 5/24/10. No change to policy statement or coverage criteria. (adn)
- 1/04/11 Added CPT codes 95800 and 95801 to the "Billing/Coding" section. Also deleted codes 0203T and 0204T. (adn)
- 9/4/12 Added a related policy and a related guideline. Added "A nasal expiratory positive airway pressure (EPAP) device is considered investigational" to the When Not Covered Section. Specialty Matched Consultant Advisory Panel review 8/15/12. Notification given 9/4/12 for policy effective date of 12/11/12. (sk)
- 1/1/13 CPT codes 95782 and 95783 added to Billing/Coding section. (sk)
- 5/14/13 Medical Director review. Added information on the Winx™ Sleep Therapy System to the Description section. Added "Single pressure, oral airway devices without forced nasal air are not considered CPAP and are considered investigational in the treatment of OSA" to the When Not Covered section. Reference added. Notification given 5/14/13 for policy effective date of 8/13/13. (sk)
- 12/31/13 New code A7047 added to Billing/Coding section. (sk)
- 12/31/13 Clarification added for a single night for a home sleep study. PAP-NAP studies are considered investigational. Reference added. Specialty Matched Consultant Advisory Panel review 8/21/13. Senior Medical Director review. Notification given 12/31/13 for policy effective date 3/11/14. (sk)
- 12/9/14 Reference added. Specialty Matched Consultant Advisory Panel review 8/26/14. Medical Director review. Information on oral appliances added to Description section. Criteria for use of oral appliances added to When Covered section. Policy Guidelines updated with information regarding effectiveness of CPAP compared to oral appliances. Notification given 12/9/2014 for policy effective date 2/10/2015. (sk)
- 2/24/15 References added. Added parasomnias to When Covered section. Added coverage for bariatric surgery and APAP to When Covered section. Clarified that unattended home sleep studies are considered investigational in children younger than 18 years of age. (sk)
- 3/31/15 Senior Medical Director review. In section titled Medical Management of Sleep Apnea, clarified the conditions that must be met related to oral appliance usage. In Obstructive Sleep Apnea in Children section, minor changes made to increase clarity. (sk)
- 10/1/15 HCPCS code S8262 deleted from Billing/Coding section. Under IIB, changed "The device is prescribed by a treating physician, and/or dentist" to "The device is prescribed by a treating physician". Under Policy Guidelines, clarified that the medical professional "should have performed a face to face evaluation of the patient". Specialty Matched Consultant Advisory Panel review 8/26/15. Policy noticed 10/1/15 for effective 12/30/15. (sk)
- 4/29/16 Reference added. (sk)
- 9/30/16 Specialty Matched Consultant Advisory Panel review 8/31/2016. (sk)

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- 8/10/18 Reference added. Investigational statement added on palate expansion devices. Specialty Matched Consultant Advisory Panel review 8/30/2017. Notification given 8/10/2018 for policy effective date 10/12/2018. (sk)
- 1/1/19 Added the word “minimum” to criteria 1 of CPAP claims information in Policy Guidelines. (sk)

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