Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for the diagnosis and medical management of obstructive sleep apnea when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Supervised polysomnography performed in a sleep laboratory may be considered medically necessary as a diagnostic test in patients with a moderate/high pretest probability of OSA (see Considerations for the definition of risk factors) in the following situations:

1. Pediatric patients (ie, younger than 18 years of age); OR
2. When patients do not meet criteria for an unattended home sleep study; OR
3. A previous home study failed to establish the diagnosis of OSA in a patient with a high pretest probability of OSA; OR
4. A previous home study was technically inadequate; OR
5. Failure of resolution of symptoms or recurrence of symptoms during treatment; OR
6. To reevaluate the diagnosis of OSA and need for continued CPAP, eg, if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued; OR
7. When testing is done to rule out other sleep disorders such as central sleep apnea, parasomnias, narcolepsy, restless leg syndrome, or periodic limb movement disorder; OR
8. Presence of a co-morbidity that might alter ventilation or decrease the accuracy of a home sleep study, including, but not limited to heart failure, neuromuscular disease, chronic pulmonary disease, or obesity hypoventilation syndrome.

A repeated supervised PSG performed in a sleep laboratory may be considered medically necessary in patients who meet criteria for an in-laboratory PSG under the following circumstances:

1. To initiate and titrate CPAP in adult patients who have:
   - An AHI of at least 15 per hour, OR
   - An AHI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

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 (see Considerations section for criteria to perform a split-night study).

2. To initiate and titrate CPAP in children:
   - In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 10 or more may be considered severe.

3. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices
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) and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including central sleep apnea, heart failure, chronic pulmonary disease, obesity hypoventilation syndrome, narcolepsy, parasomnias, periodic limb movements of sleep or restless limb syndrome. The Considerations section defines high pretest probability.

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 (see Considerations).

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 re-titrated or possibly discontinued.

Continuous positive airway pressure (CPAP) may be considered **medically necessary** in adult or pediatric patients with clinically significant obstructive sleep apnea.

Auto-adjusting CPAP (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.

Bilevel positive airway pressure (BiPAP) or auto-adjusting CPAP (APAP) may be considered **medically necessary** in patients with clinically significant obstructive sleep apnea AND who have failed a prior trial of CPAP or for whom BiPAP is found to be more effective in the sleep lab.

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered **medically necessary** in adult patients with clinically significant OSA under the following conditions:
- OSA, defined by an apnea/hypopnea index (AHI) of at least 15 per hour or an AHI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension, AND
- A trial with CPAP has failed or is contraindicated, AND
- The device is prescribed by a treating physician, AND
- The device is custom-fitted by qualified dental personnel, AND
- There is absence of temporomandibular dysfunction or periodontal disease

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

**When Policy Topic is not covered**
Unattended (unsupervised) sleep studies are considered **investigational** in pediatric patients (i.e., younger than 18 years of age).
Multiple sleep latency testing (MSLT) is considered **not medically necessary** in the diagnosis of obstructive sleep apnea.

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

The use of an abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies is considered **investigational**. Supervised or unattended home sleep studies that do not meet the above criteria are **not medically necessary**.

**Considerations**

*Intraoral appliances used for the treatment of obstructive sleep apnea are covered under the medical benefit rather than the dental benefit.*

The performance of multiple nights of home sleep studies is considered one complete study. Home sleep testing will be paid only once per episode of testing. Additional units will be processed as duplicate.

If after the home sleep study is performed it is determined that autotitration positive airway pressure (APAP) is necessary then code E0601RR (continuous airway pressure device) should be submitted for the use of the APAP device. An evaluation and management (E/M) code may be used to report the physician service for interpretation of the data from the device to establish the setting for the CPAP/APAP device if the service was performed face to face with the patient. If no face to face contact with the patient was made, then the CPT code 94660 (continuous positive airway pressure ventilation (CPAP), initiation and management) should be used to report the physician service to interpret the data from the device.

**Risk Factors for OSA**

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

If no bed partner is available to report snoring or observed apneas, other signs and symptoms suggestive of OSA, (eg, age of the patient, male gender, thick neck, craniofacial or upper airway soft tissue abnormalities, or unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; however, at the present time, risk assessment is based primarily on clinical judgment.(1,2)

The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender) and has been shown to have 97% sensitivity and a negative predictive value of 96% (specificity of 33%) for the identification of patients with severe OSA (AHI >30).3 Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is not adequate for the diagnosis of OSA. Therefore, a follow-up PSG or home sleep study would still be required to confirm or exclude a diagnosis of OSA.

**OSA 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 body mass index greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI greater than 1.5 is considered abnormal (an AHI of 10 or more
may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. 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 study 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 testing in this population.

**Polysomnography for Other Disorders**

Polysomnography (PSG) may also be performed in patients with symptoms suggestive of narcolepsy (excessive sleepiness, cataplexy, sleep paralysis, and sleep-related hallucinations), unrefreshing sleep with daytime fatigue/sleepiness but without snoring or witnessed apneas, obesity hypoventilation syndrome (obesity with poor breathing, leading to hypoxia and hypercarbia), parasomnias, sleep-related seizure disorder, and neuromuscular disorders with sleep-related symptoms. PSG may be performed when a diagnosis of periodic limb movement disorder is considered because of complaints by the patient or an observer of involuntary repetitive limb movements during sleep and frequent awakenings, fragmented sleep, difficulty maintaining sleep, or excessive daytime sleepiness. PSG is not routinely indicated to diagnose or treat restless limb syndrome, except where uncertainty exists in the diagnosis. The four cardinal diagnostic features of restless limb syndrome include (1) an urge to move the limbs that is usually associated with paresthesias or dysesthesias, (2) symptoms that start or become worse with rest, (3) at least partial relief of symptoms with physical activity, and (4) worsening of symptoms in the evening or at night. The American Academy for Sleep Medicine (AASM) has published guidelines for PSG and related procedures for these indications.(1)

**Multiple Sleep Latency Test**

The multiple sleep latency test (MSLT) is an objective measure of the tendency to fall asleep in the absence of alerting factors, while the maintenance of wakefulness test (MWT) is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety).(4) The MSLT and MWT are not routinely indicated in the evaluation and diagnosis of OSA or in assessment of change following treatment with CPAP. The MSLT may be indicated as part of 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.(4,5) Since it is not possible to differentiate the excessive sleepiness caused by OSA and narcolepsy, the OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.

**Specialist Training**

The medical professional who is interpreting a polysomnogram or home sleep study should have training in sleep medicine and should review the raw data from polysomnography (PSG) and home sleep studies in order to detect artifacts and data loss. In addition, the treatment of patients diagnosed with OSA should be initiated and monitored by a professional with training in sleep medicine. It is important to monitor symptoms and adherence to positive airway pressure (PAP) treatment, eg, review of symptoms and device utilization between 30 and 90 days.

**Split Night Studies**

American Academy for Sleep Medicine (AASM) Practice Parameters indicate that a split-night study (initial diagnostic PSG followed by CPAP titration during PSG on the same night) is an alternative to 1 full night of diagnostic PSG followed by a second night of titration if the following 4 criteria are met(1):
a. An AHI of at least 40 is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI of 20 to 40, based on clinical judgment (eg, if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP pressure requirements, based on split-night studies, may be less accurate than in full-night calibrations.

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

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

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

Categorization of Polysomnography and Portable Monitoring

There is not full correspondence between the CPT codes and the most current categorization scheme for the different types of studies. In the 2005 practice parameters of AASM,(1) there are 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 makes a distinction 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 either be attended or unattended by a technologist. The CPT codes 95807 and 95806 distinguish polygraphic sleep studies that are attended or unattended, but there are no codes that distinguish between type 3 and type 4 sleep studies. A wide variety of portable monitors and proprietary automated scoring systems are being tested and marketed, but the optimum combination of sensors and scoring algorithms is currently unknown. Current recommendations are that the portable monitoring device have 4 channels (oxygen saturation, respiratory effort, respiratory airflow, and heart rate) and allow review of the raw data. Type IV monitors with fewer than 3 channels are not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional with training in sleep medicine in order to detect artifacts and data loss.

Attended Studies

1. CPT Code 95807: Sleep study, simultaneous recording of ventilation, respiratory effort, electrocardiogram (ECG) or heart rate, and oxygen saturation, attended by a technologist.
2. CPT Code 95808: Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist.
3. CPT Code 95810: Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist.
4. CPT Code 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.
5. CPT Code 95782: Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist.
6. CPT Code 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 Study**
CPT Code 95806: Sleep study, unattended, simultaneous recording of heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement). (Note that this CPT code is identical to 95807 except that the study is not monitored.)

Effective January 1, 2011, there are additional CPT codes for unattended sleep studies:
- 95800: Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time
- 95801: Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)

These differ from 95806 in the description of a single respiratory sensor (either airflow or peripheral arterial tone) instead of the standard configuration of both respiratory effort and respiratory airflow (ventilation).

Use of overnight oximetry alone would be indicated by 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 BiPAP devices, E0470 and E0471. HCPCS codes do not distinguish among fixed CPAP or BiPAP devices.

**Description of Procedure or Service**
Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. OSA is typically diagnosed by overnight monitoring with polysomnography (PSG). Medical management of OSA may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous positive airway pressure (CPAP) during sleep.

Current literature indicates that evaluation of OSA should be by clinical evaluation and overnight monitoring, either by attended PSG or by portable unattended home monitoring under qualified supervision and that this may be followed by a trial of auto-adjusting positive airway pressure (APAP) to evaluate efficacy and adjust pressure.

- Portable monitoring may be conducted in adult patients with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation.
- A positive portable monitoring study with at least 4 channels of recording, including arterial oxygen saturation, airflow and respiratory effort, has a high positive predictive value for OSA and can be used as the basis for a continuous positive airway pressure (CPAP) trial to determine 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.
- Due to the probability of artifacts or loss of data, raw data from the portable monitoring device should be interpreted by a sleep specialist. Follow-up and review of the APAP trial is also needed.

Although evidence indicates that portable monitoring can be a safe and effective method to evaluate OSA, the variety of portable monitoring devices available and the lack of standardization remains problematic. Additional study is needed to determine the most reliable types of devices and combinations of sensors. Questions also remain about the specific training of the medical personnel required to diagnose OSA without increasing risk of misdiagnosis. Based on the current evidence, use of portable monitoring may be considered medically necessary in adult patients considered to be at
high risk for OSA, with clinical evaluation and follow-up conducted by a medical professional experienced in the diagnosis and treatment of sleep disorders.

Use of the novel expiratory positive airway pressure (EPAP) device has been reported in several prospective case series and 1 industry-sponsored randomized controlled trial. The main finding of this study was a decrease in Apnea/Hypopnea Index (AHI) with minor impact on oxygenation and the Epworth Sleepiness Scale (ESS). No evidence was identified on the oral 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 (positive airway pressure nap) 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.

Background

Description of Disease
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 a 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 (ESS), 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.

A hallmark sign 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. Upper airway resistance syndrome (UARS) is a variant of OSA that is characterized by a partial collapse of the airway, resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha electroencephalographic (EEG) arousals (“respiratory event-related arousals” [RERAs]). The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, ie, cars, trucks, or heavy equipment, while OSA in children may result in neurocognitive impairment and behavioral problems.

OSA can also affect the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to daytime sleepiness. 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.(2)

Diagnosis
The gold standard diagnostic test for sleep disorders is a polysomnogram performed in a sleep laboratory.(1) A standard polysomnogram includes EEG, submental electromyogram (EMG) and electro-oculogram (to detect rapid eye movement [REM] sleep) for sleep staging. PSG 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 become dislodged during the night. In addition, an attendant is able to identify severe OSA in the first part of the night and titrate CPAP in the second part of the night, commonly known as a “split-night” study. If successful, this strategy can eliminate the need for an additional PSG
for CPAP titration. Auto-adjusting positive airway pressure (APAP) may also be used to determine the most effective pressure.

Typically, the evaluation of OSA includes sleep staging to assess arousals from sleep and determination of the frequency of apneas and hypopneas. In adults, apnea is defined as a drop in the peak signal excursion (airflow) by 90% or more of pre-event baseline for at least 10 seconds. Hypopnea in adults is scored when the peak signal excursions drop by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 3% arterial oxygen desaturation or an 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. RDI may be defined as the number of apneas, hypopneas, and RERAs per hour of sleep. When sleep onset and offset are unknown, eg, in home sleep studies, the RDI may be calculated based on the number of apneas and hypopneas per hour of recording time. A diagnosis of OSA is accepted when an adult patient has an AHI greater than 5 and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI equal to or greater than 15 is typically considered moderate OSA, while an AHI greater than 30 is considered severe OSA.

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. An apnea is scored when peak signal excursions (airflow) drop by at least 90% of pre-event baseline and the event meets duration and respiratory effort criteria for an obstructive, mixed, or central apnea. A hypopnea is scored in children when the peak signal excursions drop by at least 30% of pre-event baseline for at least the duration of 2 breaths in association with either a 3% or greater oxygen desaturation or an arousal. In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 10 or greater may be considered severe. Although there is poor correlation between AHI and OSA symptoms, an increase in mortality is associated with an AHI of greater than 15 in adults. Mortality has not been shown to be increased in adult patients with an AHI between 5 (considered normal) and 15. A variety of devices have been developed specifically to evaluate OSA at home. These range from portable full PSG systems to single channel oximeters. Available devices evaluate different parameters, which may include oximetry, respiratory and cardiac monitoring, and sleep/wake activity, but 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

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure (PAP) therapy (ie, fixed CPAP, bilevel PAP [BiPAP], or auto-adjusting PAP [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. BiPAP is similar to CPAP, but these devices are capable of generating 2 adjustable pressure levels. APAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been hypothesized that both BiPAP 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/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.

Other devices that are being marketed for the treatment of OSA are PROVENT and Winx™. PROVENT is a single use nasal expiratory resistance valve device containing valves that are inserted into the nostrils and secured with adhesive. The Winx™ system uses oral pressure therapy (OPT) for the treatment of OSA. 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.

Surgical management of OSA (ie, adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in a separate policy.

Rationale
This policy was created in 1996 and updated periodically using the MEDLINE database. The most recent literature update was performed through May 29, 2014.

As described in Cochrane reviews from 2006, treatment of obstructive sleep apnea (OSA) with continuous positive airway pressure (CPAP) or oral appliances has been shown to improve objective and subjective symptoms in patients with OSA.(7,8) This policy focuses, therefore, on patient selection criteria for polysomnography (PSG), or sleep study. In addition, the use of expiratory positive airway pressure (EPAP), oral pressure therapy (OPT), auto-adjusting positive airway pressure (APAP) or bilevel positive airway pressure (BiPAP) in patients with OSA is reviewed.

Diagnosis and Treatment
In 2011, the Agency for Healthcare Research and Quality (AHRQ) conducted a comparative effectiveness review (CER) on the diagnosis and treatment of OSA in adults.(9) The CER found strong evidence that an AHI greater than 30 events/hour is an independent predictor of all-cause mortality, with low or insufficient evidence for an association between AHI and other clinical outcomes. The CER found moderate evidence that type 3 and type 4 monitors may have the ability to accurately predict 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. Despite no or weak evidence for an effect of CPAP on clinical outcomes, given the large magnitude of effect on the intermediate outcomes of AHI, Epworth Sleepiness Scale (ESS), and arousal index, the strength of evidence that CPAP is an effective treatment to alleviate sleep apnea signs and symptoms was rated moderate. The strength of the evidence that mandibular advancement devices improve sleep apnea signs and symptoms was rated moderate, and there was moderate evidence that CPAP is superior to mandibular advancement devices in improving sleep study measures.

An improvement in postoperative outcomes with CPAP was suggested in a 2014 matched comparison between patients with OSA who had been diagnosed prior to surgery (2,640 surgeries), those who had not been diagnosed until up to 5 years after surgery (1,571 surgeries), and 16,277 surgeries from patients without a diagnosis of OSA out of 21 years of available data.(10) In multivariate analysis, the risk of respiratory complications was increased for both diagnosed and undiagnosed OSA patients compared to controls (odds ratio [OR] 2.08, p < 0.001). Diagnosed OSA was not associated with a significant risk reduction in respiratory complications. However, the risk of cardiovascular complications, primarily cardiac arrest and shock, was increased in OSA patients who had not been diagnosed until after surgery (relative risk 2.20, 95% CI 1.16 – 4.17, p=0.02), but not in those who had been diagnosed prior to surgery (relative risk 0.75, 95% CI 0.43-1.28, p=0.29), and the difference between groups was significant at p=0.009. There was a significant trend of increased risk with increasing OSA severity. Limitations of the study include the inability to determine whether CPAP was used peri-operatively, and since BMI could not be determined, potential confounding from the close association between obesity and OSA.

Ambulatory Diagnosis and Management by a Sleep Specialist
Two large randomized controlled trials have been published that compare home-based diagnosis with a portable monitor and titration with APAP versus laboratory-based diagnosis with PSG and titration with CPAP.

In 2012 Rosen et al published results from the HomePAP study, reporting that a home-based strategy for diagnosis and treatment of OSA was noninferior to in-laboratory PSG.(11) HomePAP was an
independently funded multicenter trial of 373 patients with a high pretest probability of moderate to severe OSA. All of the study sites were accredited by a professional sleep medicine society and staffed by sleep medicine specialists. Patients were randomized to diagnosis with limited channel portable sleep studies (airflow, respiratory effort, oxygen saturation, electrocardiogram, and body position) and titration with APAP, or to laboratory-based PSG with CPAP titration. Repeat in-lab PSG was required in 11.1% of patients while the technical failure rate in the home arm, requiring in-lab PSG, was 21.4%. The 2 strategies were similar for acceptance of CPAP therapy, titration pressures, effective titrations, time to treatment, and improvement in ESS scores. Kuna et al conducted a noninferiority trial that compared home testing with a type 3 portable monitor followed by at least 3 nights of APAP versus in-laboratory titration and testing in 296 patients.(12) Patients with an AHI of 15 or more on home monitoring were scheduled for 4- to 5-day APAP titration, while patients with an AHI of less than 15 per hour on home monitoring underwent in-laboratory PSG. Improvement in ESS, Center for Epidemiologic Studies Depression Scale (CESD), Mental Component Summary of the SF-12, and Functional Outcomes of Sleep Questionnaire (FOSQ) was similar for home-based and hospital-based treatment, meeting noninferiority parameters. Other randomized studies have also found outcomes to be similar between home diagnosis and treatment in comparison with hospital-based diagnosis (PSG) and treatment (titration) when both strategies are supervised by a sleep medicine specialist.(13,14) In addition, use of unattended home PSG has also been reported as an alternative to in-lab PSG for patients with co-morbidities.(15)

Analysis of data from the Swiss respiratory polygraphy registry found that in patients selected for portable monitoring (based on high clinical suspicion of OSA by licensed pulmonary physicians by a combination of hypersomnia, snoring, or observed apneas), confirmation or exclusion of sleep disordered breathing was possible in 96% of the 8,865 diagnostic sleep studies.(16) From these type 3 studies (4 channels including airflow and respiratory movement, heart rate or electrocardiogram [ECG], and oxygen saturation), 3.5% were not conclusive and required additional PSG.

Section Summary
Results of several randomized controlled trials indicate that for patients with a high probability of moderate to severe sleep apnea and no contraindications, a home-based strategy with a multiple channel device that is overseen by a sleep specialist results in outcomes that are roughly equivalent to in-hospital diagnosis and management.

Use of APAP for Diagnosis and Treatment with Supervision by a Sleep Specialist
Mulgrew et al published a randomized validation study of the diagnosis and management of OSA with a single channel monitor followed by APAP.(17) They developed a diagnostic algorithm that was found to have a 94% positive predictive value for moderate to severe OSA assessed by PSG. Patients who passed the screening (n=68) were randomized to either attended in-laboratory PSG with CPAP titration or to home monitoring with a portable APAP unit. No difference was observed between lab-PSG and home-managed patients in any of the outcome measures. Senn et al assessed whether an empiric approach, using only a 2-week trial of APAP, could be effective for the diagnosis of OSA.(18) 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 sensitivity of 80%, specificity of 97%, and positive and negative predictive values of 97% and 78%, respectively.

Primary Care Versus Specialist Care
A 2013 randomized noninferiority trial by Chai-Coetzer et al compared primary care versus specialist sleep center management of OSA.(19) Prospective participants were screened for eligibility by 34 primary care physicians using a screening questionnaire (n=402) followed by overnight oximetry (n=301). Inclusion criteria were a score of 5 or more on the questionnaire, at least 16 events per hour of oxygen desaturation (≥3%), and an ESS of 8 or higher or persistent hypertension. An ambulatory sleep
study with the recommended number of channels was not performed. Enrolled subjects were then randomly allocated to management by a primary care physician and community-based nurse, both of whom received brief training in sleep medicine (n=81), or to a sleep medicine specialist (n=74). CPAP pressure was determined through either 3 days of APAP or PSG titration. At the 6-month follow-up, 63% of patients in the primary care group and 61% of patients in the specialist groups were using CPAP. ESS scores improved to a similar extent in both groups, from a mean score of 12.8 to 7.0 in the primary care group and from 12.5 to 7.0 in the specialist group. There were similar improvements in secondary outcomes (FOSQ, Sleep Apnea Symptoms Questionnaire, SF-36 Health Survey) for the 2 groups.

Peripheral Arterial Tone

In 2009, CMS issued a coverage decision to accept use of a sleep testing device that included actigraphy, oximetry, and peripheral arterial tone to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA.(20) (See Medicare National Coverage section below) A literature review of this technology in September 2009 identified a review of use of peripheral arterial tone for detecting sleep disordered breathing.(21) This review includes the critical evaluation of a number of studies comparing the Watch-PAT™ with laboratory-based PSG. Studies that included appropriate study populations (patients referred for evaluation of OSA or following CPAP treatment) are described below.

Berry et al randomized 106 patients who had been referred for a sleep study for suspected OSA at a local Veterans Administration center to portable monitoring followed by APAP (PM-APAP) or to PSG for diagnosis and treatment.(22) Patients were screened with a detailed sleep and medical history questionnaire, and patients on -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, and in the portable monitoring arm, 4 of 53 patients (8%) were found not to have OSA. Treatment outcomes were similar in the 2 groups, with a 7-point improvement in ESS score, 3-point improvement in the FOSQ, and a machine estimate of residual AHI of 3.5 in the PM-APAP group and 5.3 in the PSG group.

Pittman et al evaluated residual OSA in 70 patients who had self-reported adherence to CPAP for at least 3 months.(23) Exclusion criteria for the study included use of alpha-adrenergic blockers. Compared to concurrently recorded PSG, the area under the curve (AUC) from receiver operator characteristic (ROC) analysis for RDI greater than 15 was 0.95 (85% sensitivity and 90% specificity). Specificity decreased dramatically at lower cutoffs (67% for RDI >10, 47% for RDI >5). Another small study of 37 consecutive patients referred to a sleep center for OSA reported a high correlation between PSG and concurrently recorded Watch-PAT RDI (r=0.93).(24) (Correlation coefficients are not considered to be as meaningful as estimates of sensitivity and specificity.) Sensitivities for AHIs greater than 5, 15, and 35 in this study were 94%, 96%, and 83%, respectively. Specificity was reported at 80%, 79%, and 72%, respectively, for these thresholds.

Penzel et al raised concern about the specificity of this device in an independently conducted small study of 21 patients with suspected sleep apnea.(25) The study found that for 16 of the 17 subjects with adequate recordings, the number of Watch-PAT events was greater than the number of respiratory events. The device was found to have reasonable reliability and to be very sensitive to arousal, although since arousals are not unique to apnea events, the study concluded that the specificity of the Watch-PAT is limited. Questions also remain about the clinical utility of the indirect measure of peripheral arterial tone in place of directly measuring airflow and respiratory effort. In a 2004 report, Pittman et al noted other potential disadvantages of the Watch-PAT, including the inability to differentiate between the type of respiratory event (eg, obstructive, central, mixed, or hypopnea) or to identify body position, and susceptibility to artifact from arrhythmias.(26) It is noteworthy that the American Academy of Sleep Medicine (AASM) has not changed their 2007 guidelines, recommending that portable monitors should minimally record airflow, respiratory effort, and blood oxygenation, using biosensors conventionally used for in- laboratory PSG.(27) At this time, evidence is insufficient to support a change in the sensors required for portable monitoring.
Telemonitoring
No studies have been identified that compared unattended home sleep studies versus remotely monitored home sleep studies using type 3 devices. Two studies were identified that evaluated telemonitored PSG and 1 study was identified that used telemonitoring of APAP.
The most relevant study is a 2008 report by Kayyali et al that used real-time monitoring of a 14-channel wireless device in the patient’s own home.(28) Patients came to the physician’s office for application of the electrodes and sensors, then took a laptop computer home with them and called the sleep technologist when they were going to bed. Using a wearable radiofrequency transmitter, data were sent to the laptop computer in the patient’s home, which then transmitted the data to a monitoring center via cellphone. If any of the channels or video camera needed adjustments, the technologist would call the patient for intervention. In this validation study, 1 of 10 overnight PSG recordings required a phone call in the middle of the night to adjust an airflow sensor.

A study from 1999 compared consecutive nights of telemonitored PSG versus home PSG in 99 patients.(29) The telemonitored PSG took place in community hospitals that did not have a dedicated sleep center, and the sleep technician who was monitoring the studies remotely could call the on-duty nurse to attempt to correct the technical problem. For the home PSG, electrodes were placed by an experienced technician and the patient went home for the night, returning to the sleep laboratory the next morning to return the equipment and the recording. The 2 nights of PSG were conducted in a randomized order. With a primary endpoint of at least 3 hours of legible recordings, the failure rate for home studies was 23.4% and the failure rate of telemonitored hospital studies was 11.2%. It was noted that there is a risk of detachment of the PSG electrodes on the way home. This would not be as much of an issue with a type 3 device, particularly if the set-up was performed in the patient’s home.

Monitoring of APAP use by daily transmission to a web-based database and review by a research coordinator was shown to improve compliance to PAP therapy (191 vs 105 min/d).(30) For the telemedicine arm of this randomized trial, 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 greater than 30% of the night, less than 4 hours of use for 2 consecutive nights, machine measured AHI 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, 0.7 for controls).

Treatment

BiPAP and APAP
A 1995 study by Reeves-Hoche et al randomized adult patients with OSA to receive either CPAP or BiPAP.(31) The authors found that patient complaints and effective use were similar in both groups but that the dropout rate was significantly higher in the CPAP group. This study suggests that BiPAP should be limited to those patients who have failed a prior trial of CPAP. However, two randomized trials comparing CPAP and BiPAP in children found no difference in adherence between the 2 devices.(32,33) The 2011 AHRQ CER 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.(9)

Evidence-based guidelines from AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals.(34-37) As indicated in the 2011 AHRQ CER, increased compliance with APAP devices has not been well-documented in clinical trials.(38-40) Thus, the issues associated with APAP are similar to BiPAP; ie, APAP may be considered medically necessary in patients who have failed a prior trial of CPAP. PAP-NAP

In 2008, Krakow et al reported use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP.(41) 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 of these patients had anxiety, fear, and/or resistance regarding PAP therapy or the diagnosis
of OSA. Thirty-nine patients who could not be persuaded to 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 consisted of 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 EEG leads); PAP therapy during 1 to 2 hours in bed in which the patient has the possibility of falling asleep with the mask in place; and posttest follow-up. Thirty-five of 39 nap-tested patients subsequently scheduled and completed an overnight titration or split-night study with full PSG. The effect of the PAP-NAP intervention on compliance was compared to historical controls (n=38) with 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 compared with 23% of controls. Adherence, defined as at least 5 days per week with an average of at least 4 hours per day, was 56% in the PAP-NAP group and 17% in controls.

This single study of PAP-NAP is not sufficient evidence to form conclusions on the efficacy of this approach in improving compliance with CPAP. The patient population was highly selected and the behavioral intervention may be dependent on the specific clinicians providing treatment. In addition, historical controls were used, and they were not well-matched to the study population. For these reasons, the internal validity and generalizability of the results are uncertain.

**Oral Appliance Therapy**

A 2013 randomized crossover trial by Phillips et al found similar health outcomes after 1 month of CPAP or oral appliance therapy (OAT) in 126 patients (82% with moderate to severe OSA, AHI \(\geq 15\))(42). CPAP was more effective than mandibular advancement therapy in reducing AHI (CPAP AHI=4.5, OAT AHI=11.1), but patient-reported compliance was higher with OAT (6.5 vs 5.2 hours/night). Neither treatment improved the primary outcome of 24-hour ambulatory blood pressure, except in a subgroup of patients who were initially hypertensive. The 2 treatments resulted in similar improvements in sleepiness (improvement, 1.6-1.9), FOSQ (improvement, 1.0), some measures on driving simulator performance, and disease-specific quality of life (QOL). OAT was superior to CPAP in 4 domains on the SF-36.

**Nasal EPAP**

One randomized controlled trial and several prospective case series have been published with the PROVENT device.

In 2011, Berry et al reported an industry-sponsored multicenter double-blind randomized sham-controlled trial of nasal EPAP.(43) Two hundred fifty patients with OSA and an AHI of 10 or more per hour were randomized to nasal EPAP (n=127) or a sham device (n=123) for 3 months. PSG was performed on 2 nights (device-on, device off, in a random order) at week 1 (92% follow-up) and after 3 months of treatment (78% follow-up). EPAP reduced the AHI from a median of 13.8 to 5.0 (-52.7%) at week 1 and from 14.4 to 5.6 (-42.7%) at 3 months. This was a significantly greater reduction in AHI than the sham group (-7.3% at week 1, -10.1% at 3 months). Over 3 months, the decrease in ESS 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 the ESS 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 per hour on the device-off PSG night. The oxygenation results (oxygenation desaturation index and % of total sleep time with SpO2 <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 reduced to less than 10 (if device-off AHI was 10 or more), was greater in the EPAP group at 1 week (62% vs 27.2%) and 3 months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing the study due to adverse events. Overall, the validity of these results is limited by the high dropout rate, and the clinical significance of the results is uncertain.
An open-label extension of the 2011 randomized study by Berry et al evaluated 12-month safety and durability of the treatment response in patients who had an initial favorable response to EPAP. Included were 41 patients (32% of 127) 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 per 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 to the device-off PSG. Of the 51 patients (40% of 127) eligible, 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). Over 12 months of treatment, the ESS 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, and the most frequently reported adverse events were difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study is limited by the inclusion of responders only and by the potential for a placebo effect on the ESS. However, the data suggest that some patients may respond 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 1 in 4 patients. Additional controlled studies are needed to distinguish between these alternatives.

**Oral Pressure Therapy**

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

**Clinical Input Received 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.

### 2009

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, the input supported the use of PSG, portable sleep monitoring tests, multiple sleep latency test, and CPAP for adults as described in the policy. The March 2009 update includes the reviewer’s recommendations for clarifications and modifications to the policy statements.

### 2010

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

### 2014

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. The input focused on routine screening of patients scheduled to undergo bariatric surgery. There was consensus that routine screening is considered medically necessary in this population due to the high prevalence of OSA in patients with a BMI greater than 40, combined with the increased rate of peri-operative complications in patients with OSA. 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.

**Summary of Evidence**

Current literature indicates that evaluation of obstructive sleep apnea (OSA) should be by clinical evaluation and overnight monitoring, either by attended polysomnography (PSG) or by portable unattended home monitoring under qualified supervision and that this may be followed by a trial of auto-adjusting positive airway pressure (APAP) to evaluate efficacy and adjust pressure.

- **Portable monitoring** may be conducted in adult patients with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation.
- A positive portable monitoring study with at least 4 channels of recording, including 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 (continuous positive airway pressure) trial to determine 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.
- Due to the probability of artifacts or loss of data, raw data from the portable monitoring device should be interpreted by a sleep specialist. Follow-up and review of the APAP trial is also needed.

Although evidence indicates that portable monitoring can be a safe and effective method to evaluate OSA, the variety of portable monitoring devices available and the lack of standardization remains problematic. Additional study is needed to determine the most reliable types of devices and combinations of sensors. Questions also remain about the specific training of the medical personnel required to diagnose OSA without increasing risk of misdiagnosis. Based on the current evidence, use of portable monitoring may be considered medically necessary in adult patients considered to be at high risk for OSA, with clinical evaluation and follow-up conducted by a medical professional experienced in the diagnosis and treatment of sleep disorders.

Use of the novel EPAP device has been reported in several prospective case series and 1 industry-sponsored randomized controlled trial. The main finding of this study was a decrease in Apnea/Hypopnea Index (AHI) with minor impact on oxygenation and the Epworth Sleepiness Scale (ESS). No evidence was identified on the oral 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.

**Practice Guidelines and Position Statements**

The patient selection criteria for a PSG or sleep study require an estimate of the pretest probability of OSA, based on the signs and symptoms of OSA. Ideally, one would like to know the necessity of a PSG (ie, with electroencephalography [EEG]) versus a sleep study (without EEG). A detailed analysis of these issues is beyond the scope of this policy. However, in 1997 the American Sleep Disorders Association (now the American Academy of Sleep Medicine [AASM]) published practice parameters for PSG and related procedures; these were most recently updated in 2005.(1,45) The guidelines suggested that patients had a 70% likelihood of having an AHI index of at least 10 if all of the following were present: habitual snoring, excessive daytime sleepiness, a body mass index greater than 35, and observed apneas. In 2005, full-night PSG was recommended for the diagnosis of sleep-related breathing disorders and for PAP titration in patients with an RDI of at least 15 per hour, or with an RDI of at least 5 per hour in a patient with excessive daytime sleepiness.(1) For patients in the high-pretest-probability stratification group, an attended cardiorespiratory sleep study (type 3 with respiratory effort, airflow, arterial oxygen saturation, and electrocardiogram [ECG] or heart rate) was considered an acceptable alternative to full-night PSG, provided that repeat testing with full-night PSG was permitted for symptomatic patients who had a negative cardiorespiratory sleep study finding.
Portable monitoring (PM) devices were addressed by a joint project of AASM, the American Thoracic Society, and the American College of Chest Physicians in 2003. In 2007 AASM issued revised guidelines for the use of unattended portable monitors, recommending that portable monitors should minimally record airflow, respiratory effort, and blood oxygenation, with biosensors conventionally used for in-laboratory PSG, and that testing be performed by an experienced sleep technologist and scored by a board-certified sleep medicine specialist under the auspices of an AASM-accredited comprehensive sleep medicine program.

The 2005 AASM guidelines gave a recommendation of standard for PSG when a diagnosis of periodic limb movement disorder is considered because of complaints by the patient or an observer of repetitive limb movements during sleep and frequent awakenings, fragmented sleep, difficulty maintaining sleep, or excessive daytime sleepiness. PSG is not routinely indicated to diagnose or treat restless legs syndrome, except where uncertainty exists in the diagnosis.

Evidence-based guidelines on BiPAP, APAP, and dental appliances have been published by AASM. The Practice Parameters provided a recommendation of “guideline” (moderate clinical certainty) that although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer oral appliances to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change. Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Oral appliances should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures. There was moderate clinical certainty that BiPAP was appropriate as an optional therapy in some cases in which high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present. APAP was not recommended to diagnose OSA, for split-night studies or for patients with heart failure, significant lung disease such as chronic obstructive pulmonary disease, patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (eg, obesity hypoventilation syndrome), patients who do not snore, and patients who have central sleep apnea syndromes. Unattended APAP in patients without significant comorbidities was considered an option (uncertain clinical use). The guidelines indicated that patients being treated on the basis of APAP titration must have close clinical follow-up to determine treatment effectiveness and safety, especially during the first few weeks of PAP use, and a reevaluation and, if necessary, a standard CPAP titration should be performed if symptoms do not resolve or if the APAP treatment otherwise appears to lack efficacy.

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

The American Academy of Pediatrics (AAP) published a 2012 guideline 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 updates AAP’s 2002 guidelines. AAP recommends that all children/adolescents should be screened for snoring, and PSG should be performed in children/adolescents with snoring and symptoms/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/adolescents range from 1.2% to 5.7%. Adenotonsillectomy is recommended as the first line of 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 is recommended if adenotonsillectomy is not performed or if OSA persists postoperatively. Weight loss is 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.

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

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

The American Academy of Craniofacial Pain Task Force on Mandibular Advancement Oral Appliance Therapy for Snoring and Obstructive Sleep Apnea published a position paper in 2013. The position paper states that oral appliance therapy is recognized as an effective therapy for many with primary snoring and mild to moderate OSA, as well as those with more severe OSA who cannot tolerate PAP therapies, but that oral appliance therapy has the potential to cause adverse effects including temporomandibular joint (TMJ) pain and dysfunction. The authors recommend that dentists engaged in, or who wish to engage in, the assessment and management of patients with snoring and OSA using mandibular advancement oral appliances should be properly trained and experienced in the assessment, diagnosis and management of TMJ and craniofacial pain.

American Society of Anesthesiologists (ASA) published updated guidelines in 2014 on the perioperative management of patients with obstructive sleep apnea. ASA recommends that anesthesiologist should work with surgeons to develop a protocol whereby patients in whom the possibility of OSA is suspected on clinical grounds are evaluated long enough before the day of surgery to allow preparation of a perioperative management plan, and that if this evaluation does not occur until the day of surgery, the surgeon and anesthesiologist together may elect for presumptive management based on clinical criteria or a last-minute delay of surgery. Guidance on the identification of OSA and recommended changes in the pre-operative, intra-operative, and postoperative management of patients with diagnosed or presumed OSA is provided, including the following:

- Before patients at increased perioperative risk from OSA are scheduled to undergo surgery, a determination should be made regarding whether a surgical procedure is most appropriately performed on an inpatient or outpatient basis.
- Preoperative initiation of CPAP should be considered, particularly if OSA is severe, and the preoperative use of mandibular advancement devices, oral appliances, and preoperative weight loss should be considered when feasible.
- The potential for postoperative respiratory compromise should be considered in selecting intraoperative medications. If moderate sedation is used, ventilation should be continuously monitored by capnography or another automated method if feasible, and use of CPAP or an oral appliance should be considered in patients previously treated with these modalities.
ASA provides a number of recommendations for the postoperative management of patients with OSA, such as use of regional analgesic techniques, reduction of opioid requirements and sedative agents, supplemental oxygen or CPAP, avoidance of supine positions, and for patients who are hospitalized, continuous pulse oximetry monitoring after discharge from the recovery room.

The American Society of Metabolic and Bariatric Surgery (ASMBS) Clinical Issues Committee published guidelines on the peri-operative management of obstructive sleep apnea in 2012. The guidelines note that while some reports in the literature recommend routine screening for obstructive sleep apnea (OSA) prior to bariatric surgery, other reports suggest clinical screening only does not result in any increase in postoperative pulmonary complications after laparoscopic Roux-en-Y gastric bypass (RYGB), and that most current surgical practices refer patients with clinical symptoms of OSA for polysomnography, but do not make this a routine preoperative test prior to bariatric surgery. The ASMBS provided, based on the evidence in the literature to date, the following guidelines regarding OSA in the bariatric surgery patient and its perioperative management:

- OSA is highly prevalent in the bariatric patient population. The high prevalence demonstrated in some studies suggests that consideration be given to testing all patients, and especially those with any preoperative symptoms suggesting obstructive sleep apnea.
- 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.
- Routine pulse oximetry or capnography for post operative monitoring of patients with OSA after bariatric surgery should be utilized, but the majority of these patients do not routinely require an ICU setting.
- No clear guidelines exist upon which to base recommendations for retesting for OSA following bariatric surgery. Strong consideration should be given to retesting patients who present years after bariatric surgery with regain of weight, a history of previous OSA, and who are being reevaluated for appropriate medical and potential reoperative surgical therapy.

The American Academy of Otolaryngology–Head and Neck Surgery published clinical practice guidelines on PSG for sleep-disordered breathing prior to tonsillectomy in children in 2011. The committee made the following recommendations: before determining the need for tonsillectomy, the clinician should refer children with sleep-disordered breathing for PSG if they exhibit certain complex medical conditions such as obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidosis; the clinician should advocate for PSG prior to tonsillectomy for sleep-disordered breathing in children without any of the comorbidities listed above for whom the need for surgery is uncertain or when there is discordance between tonsillar size of physical examination and the reported severity of sleep-disordered breathing; clinicians should communicate PSG results to the anesthesiologist prior to the induction of anesthesia for tonsillectomy; clinicians should admit children with OSA documented on PSG for inpatient, overnight monitoring after tonsillectomy if they are younger than age 3 years or have severe OSA (AHI ≥10, oxygen saturation nadir <80%, or both); in children for whom PSG is indicated to assess sleep-disordered breathing prior to tonsillectomy, clinicians should obtain laboratory-based PSG, when available.

The American Thoracic Society (ATS) published 2013 Guidelines on sleep apnea and driving risk in noncommercial drivers. ATS gives a strong recommendation (based on moderate quality evidence) for treatment of confirmed OSA with CPAP to reduce driving risk. ATS defines a high-risk driver as one who has moderate to severe daytime sleepiness and a recent unintended motor vehicle crash or a near-miss attributable to sleepiness, fatigue, or inattention. Weak recommendations (based on very low-quality evidence) were made for expeditious diagnostic evaluation for patients in whom there is a high clinical suspicion of OSA and against the use of stimulant medications or empiric CPAP to reduce driving risk. In 2008 the United Kingdom’s National Institute for Health and Clinical Excellence issued guidance on CPAP treatment of OSA, based on a review of the literature and expert opinion. The recommendations included:
Moderate to severe OSA/hypopnea syndrome (OSAHS) can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person’s home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the AHI or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5 to 14 in a sleep study, moderate when the AHI is 15 to 30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

- CPAP is recommended as a treatment option for adults with moderate or severe symptomatic OSAHS. CPAP is only recommended as a treatment option for adults with mild OSAHS if: they have symptoms that affect their quality of life and ability to go about their daily activities, and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate.
- Treatments aim to reduce daytime sleepiness by reducing the number of episodes of apnea/hypopnea experienced during sleep. The alternatives to CPAP are lifestyle management, dental devices, and surgery. Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption. Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS. Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice.

The diagnosis and treatment of OSAHS, and the monitoring of the response, should be carried out by a specialist service with appropriately trained medical and support staff.

The Committee discussed the use of CPAP therapy for children and adolescents with OSAHS. The Committee heard that OSAHS is less common among children than in adults and that the clinical issues and etiology in children are different from those encountered in adults. The Committee concluded that the recommendations for CPAP should apply only to adults with OSAHS.

U.S. Preventive Services Task Force Recommendations
No U.S Preventive Services Task Force (USPSTF) recommendations for obstructive sleep apnea screening were identified.

Medicare National Coverage
The use of CPAP devices are covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adults with OSA if either of the following criteria using the AHI or RDI are met:

- AHI or RDI of 15 events per hour or more, or
- AHI or RDI between 5 and 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.

AHI or RDI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep using actual recorded number of hours of sleep (ie, the AHI or RDI may not be extrapolated or projected). 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.

In 2001, the Centers for Medicare and Medicaid Services (CMS; formerly Health Care Financing Administration), published a decision memorandum for CPAP that addressed the issue of how to define moderate to severe OSA as a guide to a coverage policy for CPAP. This review of the literature suggested that there is a risk of hypertension with an AHI greater than 15, and thus treatment is warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 and associated symptoms, the CMS document 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 a clinical evaluation and unattended home sleep monitoring using a device with at least 3 channels. The coverage of CPAP would initially be limited to a 12-week period to identify beneficiaries diagnosed with OSA who benefit from CPAP. This is a change from prior coverage, which specified that PSG must be performed in a facility-based sleep study laboratory and not in a home or a mobile facility. CMS defines AHI as the average number of episodes of apnea and hypopnea per hour of sleep, while the RDI is equal to the average number of respiratory disturbances per hour of continuous monitoring. 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 is defined in the context of the sleep test technology of interest and, for portable monitoring devices that do not measure AHI or RDI directly, does not require direct measurement of airflow.

Effective for claims with dates of service on and after March 13, 2008, CMS determines that CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under 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 a clinical evaluation and a positive:
   a. attended PSG performed in a sleep laboratory; or
   b. unattended home sleep test with a type II home sleep monitoring device; or
   c. unattended home sleep test with a type III home sleep monitoring device; or
   d. unattended home sleep test 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: Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1–7 cited here. A
clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions:

a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and types II, III, and IV home sleep test 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, and IV home sleep test, does CPAP cause clinically meaningful harm?

In March 2009, CMS issued the following national coverage decision (CAG-00405N) for the types of sleep testing devices that would be approved for coverage.(20)

CMS finds that the evidence is 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, one of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
4. A sleep testing device measuring 3 or more channels that include actigraphy, oximetry, and peripheral arterial tone 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.

References


Billing Coding/Physician Documentation Information

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)
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 (eg, thoracoabdominal movement)

95807  Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist

95808  Polysomnography; 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

A7027  Combination oral/nasal mask, used with continuous positive airway pressure device, each

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, non disposable, used with positive airway pressure device

A7047  Oral interface used with respiratory suction pump, each

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)

E0472  Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)

E0485  Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment

E0486  Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

E0561  Humidifier, non-heated, used with positive airway pressure device

E0562  Humidifier, heated, used with positive airway pressure device

E0601  Continuous airway pressure (cpap) device

G0398  Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation

G0399  Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels

Category III codes (0203T and 0204T) were replaced by category I codes (95800 and 95801) effective January 1, 2011.

Additional Policy Key Words
Watch PAT is based on actigraphy, please refer to policy 2.01.73.
Winx Sleep Therapy System

Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/06</td>
<td>New policy added to Medical and Durable Medical Equipment sections. This policy combines the previous two policies titled: Diagnostic Sleep Studies and Continuous Positive Airway Pressure CPAP, BiPAP, and AUTO CPAP.</td>
</tr>
<tr>
<td>1/1/07</td>
<td>Policy statement revised to include atrial pacing as investigational.</td>
</tr>
<tr>
<td>1/1/08</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>10/1/08</td>
<td>Interim change, updated coding.</td>
</tr>
<tr>
<td>1/1/09</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/09</td>
<td>Policy statements clarified and revised; portable monitoring may be medically necessary under specified conditions.</td>
</tr>
<tr>
<td>1/1/10</td>
<td>New Category III codes added. No policy statement changes.</td>
</tr>
<tr>
<td>1/1/11</td>
<td>Atrial pacing policy statement removed as it is beyond the scope of the current policy, other policy statements unchanged. Coding updated.</td>
</tr>
<tr>
<td>1/1/12</td>
<td>Policy statements revised to add criteria for oral appliances; policy statement added for repeated unattended (unsupervised) home sleep studies; definition of AHI for pediatrics was added; added policy statement regarding the use of unattended sleep studies for pediatrics (considered investigational).</td>
</tr>
<tr>
<td>1/1/13</td>
<td>Criteria for oral appliances clarified; nasal expiratory positive airway pressure (EPAP) added as investigational.</td>
</tr>
<tr>
<td>1/1/14</td>
<td>Oral pressure therapy added as investigational; clarification of a single night for a home sleep study; clarification of adult patients in the statement on oral appliances; PAP-NAP studies considered investigational; telemonitored home sleep studies addressed in Considerations section.</td>
</tr>
<tr>
<td>1/1/15</td>
<td>Added CPT 94762. Added &quot;Supervised or unattended home sleep studies that do not meet the above criteria are not medically necessary&quot;, removed &quot;Unattended home sleep studies are considered investigational in children (younger than 18 years of age)&quot;, removed &quot;syndrome except to exclude or confirm narcolepsy in the diagnostic workup of OSAS&quot; from investigative section, statement added that screening of bariatric surgery patients may be medically necessary. Updated and added generously to medically necessary statement on Supervised polysomnography performed in a sleep laboratory. Updated medically necessary statement regarding single unattended home sleep study. Removed medically necessary statement regarding repeat supervised polysomnography in a sleep laboratory. Medically necessary statement regarding APAP, removed 2 week trial portion. Also added screening of bariatric surgery patients may be medically necessary; revised criteria for home sleep studies and in laboratory polysomnography.</td>
</tr>
<tr>
<td>4/1/15</td>
<td>No policy statement changes. Considerations section updated with coding clarification.</td>
</tr>
</tbody>
</table>

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.