Title: Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

**Professional**
Original Effective Date: April 7, 1983
Revision Date(s): May 16, 1991; July 1, 1994; June 30, 1995; December 16, 1996; April 1, 2004; February 17, 2006; December 13, 2007; January 1, 2010; January 1, 2011; January 12, 2011; February 25, 2011; August 30, 2012; January 1, 2013; September 16, 2015
Current Effective Date: August 30, 2012

**Institutional**
Original Effective Date: June 3, 2004
Revision Date(s): February 17, 2006; December 13, 2007; January 1, 2010; January 1, 2011; January 12, 2011; February 25, 2011; August 30, 2012; January 1, 2013; September 16, 2015
Current Effective Date: August 30, 2012

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

Diagnosis
The gold standard diagnostic test for sleep disorders is a polysomnogram performed in a sleep laboratory. 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 is 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.

**Regulatory Status**
A variety of oral appliances have received marketing clearance through the U.S. Food and Drug Administration (FDA) 510(k) pathway for the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™, Lamberg SleepWell-Smarttrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, Desra, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device. FDA product code: LQZ

A number of various CPAP devices have received 510(k) clearance since 1977. BiPAP devices were first cleared for marketing by FDA in 1996. FDA product codes: BZD, MNT

In 2010, a nasal expiratory resistance valve (PROVENT®, Ventus Medical) received marketing clearance through the 510(k) process for the treatment of OSA. The Winx™ system received marketing clearance in 2012.
POLICY

BCBSKS encourages sleep study facilities to become accredited through the American Academy of Sleep Medicine (AASM) and/or the Accreditation Commission for Health Care, Inc. (ACHC) and physicians to be board certified in sleep medicine. The following criteria and documentation for medical necessity applies to all providers, regardless of their accreditation or certification level.

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

I. Diagnosis
   A. Supervised Polysomnography
      1. Supervised polysomnography performed in a sleep laboratory may be considered **medically necessary** as a diagnostic test in patients with any of the following:
         a. Observed apneas during sleep
         OR
         b. A combination of at least 2 of the following:
            1) Excessive daytime sleepiness evidenced by:
               a) an Epworth Sleepiness Scale greater than 10
               b) inappropriate daytime napping (e.g., during driving, conversation, or eating), or
               c) sleepiness that interferes with daily activities and is not explained by other conditions (this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children)
            2) Habitual snoring, or gasping/choking episodes associated with awakenings,
            3) Unexplained hypertension,
            4) Obesity, defined as a body mass index greater than 30 kg/m² in adults or greater than the 90th percentile for the weight/height ratio in pediatric patients,
            5) Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy,
            6) Neuromuscular disease
            OR
         c. Moderate or severe congestive heart failure, stroke/transient ischemic attack, coronary artery disease, or significant tachycardia or bradycardic arrhythmias in patients who have nocturnal symptoms suggestive of a sleep-related breathing disorder or otherwise are suspected of having sleep apnea
         OR
d. Symptoms suggesting narcolepsy, e.g., sleep paralysis, hypnagogic hallucinations, cataplexy
   OR

e. Violent or injurious behavior during sleep
   OR

f. Other situations (if nocturnal pulse oximetry suggests nocturnal oxygen desaturation) such as:
   1) Unexplained right heart failure
   2) Unexplained polycythemia
   3) Presence of or increase in cardiac arrhythmias during sleep
   4) Unexplained pulmonary hypertension
   OR

g. Excessive daytime sleepiness together with witnessed periodic limb movements of sleep
   OR

h. Unusual or atypical parasomnias based on patient’s age, frequency, or duration of behavior
   OR

i. Pediatrics – under 18 – with ANY of the following additional indications:
   1) behavioral problems, which may be expressed as:
      a) learning difficulties
      OR
      b) daytime neurobehavioral problems in young children
      OR
   2) hyperactivity
      OR
   3) snoring alone
      OR
   4) chronic disturbed sleep

Risk factors include:
- adenotonsillar hypertrophy
- obesity (defined as greater than the 90th percentile for the weight/height ratio)
- craniofacial anomalies, and
- neuromuscular disorders
2. Routine supervised polysomnography is **not medically necessary** for the following:
   a. To diagnose or treat restless legs syndrome
   b. To establish a diagnosis of depression
   c. For the following conditions existing alone in the absence of other features suggestive of obstructive sleep apnea:
      1) Snoring
      2) Obesity
      3) Hypertension
      4) Morning headaches
      5) Decrease in intellectual functions
      6) Memory loss
      7) Frequent nighttime awakenings
      8) Other sleep disturbances, such as insomnia (acute or chronic), night terrors, sleep walking, epilepsy where nocturnal seizures are not suspected
      9) Common uncomplicated non-injurious parasomnias

B. Unattended (unsupervised) Home Sleep Studies
1. Unattended (unsupervised) home sleep studies with a minimum of 4 recording channels (2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation) may be considered medically necessary in adult patients who are at risk for OSA and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including the following:
   a. Central sleep apnea
   b. Congestive heart failure
   c. Severe chronic pulmonary disease
   d. Obesity hypoventilation syndrome
   e. Narcolepsy
   f. Periodic limb movements in sleep
   g. Restless leg syndrome

   Note: Respiratory disturbance index may be used in place of apnea/hypopnea index (AHI) in unattended sleep studies.

2. Unattended (unsupervised) sleep studies are considered **experimental / investigational** in **pediatric** patients.
C. Repeat Supervised Polysomnography

A repeat supervised polysomnography performed in a sleep laboratory may be considered medically necessary under the following circumstances:

1. To initiate and titrate continuous positive airway pressure (CPAP) in adult patients with clinically significant OSA defined as those patients who have:
   a. An apnea/hypopnea index (AHI) of at least 15 per hour,
   **OR**
   b. An AHI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

   Note:
   - In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 is considered severe.
   - A split-night study, in which severe OSA is documented during the first portion of the study using polysomnography, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines for criteria to perform a split-night study).

   **OR**

2. Failure of resolution of symptoms or recurrence of symptoms during treatment

   **OR**

3. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices

   **OR**

4. To re-evaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued

   Note: This statement does not imply that supervised studies are needed routinely following unattended studies. This statement means a re-evaluation based on a substantial change in symptoms or in the clinical situation.

D. Repeat Unattended (unsupervised) Home Sleep Studies

Repeat unattended (unsupervised) home sleep studies with a minimum of four recording channels (2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation) may be considered medically necessary in adult patients under the following circumstances:

1. To assess efficacy of surgery or oral appliances/devices; **OR**

2. To re-evaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued.
E. Two Separate Night Studies
Two separate nights’ polysomnography studies, one for the diagnosis of sleep disorders and the second to titrate CPAP, are generally considered not medically necessary unless circumstances do not allow for half night or “split night” polysomnography with titration of CPAP performed in the second part of the study, (e.g., significant obstructive sleep apnea not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep). In these cases, a second full night’s study may then be medically necessary for CPAP titration.

F. Multiple Sleep Latency Testing
Multiple sleep latency testing is considered not medically necessary in the diagnosis of OSA except to exclude or confirm narcolepsy in the diagnostic workup of OSA syndrome.

II. Medical Management
A. CPAP
CPAP may be considered medically necessary in adult patients with clinically significant OSA defined as:
1. Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour, OR
2. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke, OR
3. For pediatric patients:
   a. AHI or RDI of at least 5 per hour, or
   b. AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.
   Note: AHI greater than 1.5 is considered abnormal, and AHI of 15 or more is considered severe.

B. Bilevel positive airway pressure or auto-adjusting CPAP may be considered medically necessary in patients with clinically significant OSA AND who have failed a prior trial of CPAP or for whom BiPAP is found to be more effective in the sleep lab.
C. Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in patients with clinically significant OSA under the following conditions:
1. OSA, defined by an apnea/hypopnea index (AHI) of at least 15 per hour or an AHI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension
   AND
2. The device is prescribed by a treating physician
   AND
3. The device is custom-fitted by qualified dental personnel.

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

D. A nasal expiratory positive airway pressure (EPAP) device is considered experimental / investigational.

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

Policy Guidelines
1. Clinically significant OSA is defined as those adult patients who have:
   - Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour, or
   - 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.

The AHI is the total number events (apnea or hypopnea) per hour of recorded sleep. The RDI is the total number events (apnea or hypopnea) per hour of recording time. An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. 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 3% oxygen desaturation.
2. The presentation of obstructive sleep apnea (OSA) in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness, and an apnea/hypopnea index (AHI) greater than 1.5 is considered abnormal (an AHI of 15 is considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. Continuous positive airway pressure (CPAP) is an option for children who are not candidates for surgery or who have an inadequate response to surgery. Clinically significant OSA is defined as those pediatric patients who have:
   - AHI or RDI of at least 5 per hour, or
   - AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity.

3. The medical professional who is requesting, performing, and evaluating a polysomnogram or home sleep study should have training in sleep medicine.

4. 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 greater than 35.

5. American Academy for Sleep Medicine (AASM) Practice Parameters indicate:
   a. A split-night study (initial diagnostic polysomnography [PSG] followed by CPAP titration during PSG on the same night) is an alternative to one full night of diagnostic PSG followed by a second night of titration if:
      1. 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 (e.g., 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.
      2. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).
      3. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM (NREM) sleep, including REM sleep with the patient in the supine position.
   b. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder (SRBD) is confirmed, but criteria 2 and 3 from above are not met.

6. Based on currently available evidence, health outcomes for CPAP and auto-adjusting CPAP appear to be comparable.
7. 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). (3) 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. (3, 4) 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.

8. 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 the AASM (2), there are 4 types of monitoring procedures:
   - type 1, standard attended in-lab comprehensive polysomnography
   - type 2, comprehensive portable polysomnography
   - type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of 4 or more channels of monitoring; and
   - type 4, continuous single or dual bioparameters, consisting of 1 or 2 channels, typically oxygen saturation, or airflow.

   Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and polysomnography are often used interchangeably. CPT coding makes a distinction between sleep studies that do not include electroencephalographic (EEG) monitoring, and polysomnography, which includes EEG monitoring. Polysomnography is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the patient’s home. There is no CPT code for “unattended” polysomnography.

9. 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 four channels (oxygen saturation, respiratory effort, respiratory airflow, and heart rate), and allow review of the raw data. Type IV
monitors with fewer than three 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.

Utilization
AASM and ACHC certified labs are exempt from prepayment review but are subject to post payment review.

RATIONALE
This policy was updated using 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. 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. The CER found strong evidence that an Apnea/Hypopnea Index (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 (2640 surgeries), those who had not been diagnosed until up to 5 years after surgery (1571 surgeries), and 16,277 surgeries from patients without a diagnosis of OSA out of 21 years of available data. 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 [RR],
2.20; 95% confidence interval [CI]. 1.16 to 4.17; p=0.02), but not in those who had been diagnosed prior to surgery (RR=0.75; 95% CI, 0.43 to 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 perioperatively, and since body mass index 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. 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. 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, Mental Component Summary of the 12-Item Short-Form Health (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. In addition, use of unattended home PSG has also been reported as an alternative to in-lab PSG for patients with comorbidities.

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 8865 diagnostic sleep studies. 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. 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. 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. 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) 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. (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. 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. Patients were screened with a detailed sleep and medical history questionnaire, and patients on α-blockers or not in sinus rhythm were excluded due to...
the type of portable monitoring device used (Watch-PAT™ 100). Of the 53 patients randomized to PSG, 6 (11%) did not have PSG-defined OSA, 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 α-adrenergic blockers. Compared with concurrently recorded PSG, the area under the curve (AUC) from receiver operator characteristic (ROC) analysis for Respiratory Disturbance Index (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.\textsuperscript{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).\textsuperscript{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 H\textsubscript{2}O. 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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{9}

Evidence-based guidelines from AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals.\textsuperscript{34-37} As indicated in the 2011 AHRQ CER, increased compliance with APAP devices has not been well-documented in clinical trials.\textsuperscript{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.\textsuperscript{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 ≥15). 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. 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. 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), was greater in the EPAP group at 1 week (62% vs 27.2%) and 3 months (50.7%
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 Input
Input was received from 5 physician specialty societies (6 reviewers) and 3 academic medical centers in 2009. Professional society guidelines and position statements were also reviewed. In general, 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 Input
Input was received from 1 physician specialty society and 6 academic medical centers (8 reviewers) in 2010. 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 Input
Input was received from 7 physician specialty societies (8 reviewers) and 4 academic medical centers (6 reviewers) 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 body mass index greater than 40, combined with the increased rate of perioperative 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 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 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 (i.e., 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 Respiratory Disturbance Index 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 devices were addressed by a joint project of AASM, the American Thoracic Society, and the American College of Chest Physicians in 2003.46,47 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.27

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.1 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.34-37 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.37
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
2011.49 “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.50,51 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.52 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 preoperative, intraoperative, 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 pre-operative 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 intra-operative 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 perioperative 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 postoperative 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 mucopolysaccharidoses; 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 recommendations for obstructive sleep apnea screening were identified.
CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

94660  Continuous positive airway pressure ventilation (CPAP), initiation and management
94762  Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)
95782  Polysomnography, younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783  Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95800  Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time
95801  Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)
95805  Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95806  Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
95807  Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808  Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810  Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811  Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist
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
A7030  Full face mask used with positive airway pressure device, each
A7031  Face mask interface, replacement for full face mask, each
A7032  Cushion for use on nasal mask interface, replacement only, each
A7033  Pillow for use on nasal cannula type interface, 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
A7044  Oral interface used with positive airway pressure device, each
A7045  Exhalation port with or without swivel used with accessories for positive airway devices, replacement only
E0470  Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471  Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0485  Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
E0486  Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
E0561  Humidifier, non-heated, used with positive airway pressure device
E0562  Humidifier, heated, used with positive airway pressure device
E0601  Continuous airway pressure (CPAP) device
E1399  Durable medical equipment, miscellaneous
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 study test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400  Home sleep study test (HST) with type IV portable monitor, unattended; minimum of 3 channels

**Attended Studies**

- **CPT Codes:** 95807, 95808, 95810, 95811, 95782, 95783.

**Unattended Study**

- **CPT Code:** 95806 (Note that this CPT code is identical to 95807 except that the study is not monitored.) 95800, 95801 (These differ from 95806 in the description of a single respiratory sensor [either air flow or peripheral arterial tone] instead of the standard configuration of both respiratory effort and respiratory airflow [ventilation]).
- Use of overnight oximetry alone would be indicated by CPT code 94762.

**HCPCS Codes**

- There is 1 HCPCS code identifying a CPAP device, E0601, and 2 HCPCS codes for BiPAP devices: E0470 and E0471. The HCPCS codes do not distinguish among fixed CPAP or BiPAP devices and auto-adjusting CPAP devices.
- In 2008, Medicare created some G codes to facilitate their national coverage decision: G0398, G0399, G0400.
- Beginning in 2014, there is a HCPCS code for the oral interface used with devices such as the Winx system:
DIAGNOSES

These diagnoses are otherwise subject to medical policy as stated above.

Covered Diagnoses

ICD-9 Diagnoses
327.10 Organic hypersomnia, unspecified
327.11 Idiopathic hypersomnia with long sleep time
327.12 Idiopathic hypersomnia without long sleep time
327.13 Recurrent hypersomnia
327.20 Organic sleep apnea, unspecified
327.21 Primary central sleep apnea
327.23 Obstructive sleep apnea (adult) (pediatric)
327.25 Congenital central alveolar hypoventilation
327.29 Other organic sleep apnea
347.00 Narcolepsy; without cataplexy
347.01 Narcolepsy; with cataplexy
347.10 Narcolepsy in conditions classified elsewhere; without cataplexy
347.11 Narcolepsy in conditions classified elsewhere; with cataplexy
780.09 Alteration of consciousness; Other (somnolence)
780.51 Sleep disturbances, insomnia with sleep apnea, unspecified
780.53 Sleep disturbances, hypersomnia with sleep apnea, unspecified
780.54 Other hypersomnia
780.57 Sleep disturbances, unspecified sleep apnea

ICD-10 Diagnoses (Effective October 1, 2015)
G47.10 Hypersomnia, unspecified
G47.11 Idiopathic hypersomnia with long sleep time
G47.12 Idiopathic hypersomnia without long sleep time
G47.13 Recurrent hypersomnia
G47.30 Sleep apnea, unspecified
G47.31 Primary central sleep apnea
G47.33 Obstructive sleep apnea (adult) (pediatric)
G47.35 Congenital central alveolar hypoventilation syndrome
G47.39 Other sleep apnea
G47.411 Narcolepsy with cataplexy
G47.419 Narcolepsy without cataplexy
G47.421 Narcolepsy in conditions classified elsewhere with cataplexy
G47.429 Narcolepsy in conditions classified elsewhere without cataplexy
R40.0 Somnolence

REVISIONS

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Contains Public Information
Revised wording to current medical policy wording from:

"BCBSKS encourages sleep study facilities to become accredited through the American Academy of Sleep Medicine (AASM) and/or the Accreditation Commission for Health Care, Inc. (ACHC) and physicians to be board certified in sleep medicine. The following criteria and documentation for medical necessity applies to all providers, regardless of their accreditation or certification level.

Polysomnography is indicated:
- for diagnosis of sleep related breathing disorders,
- for continuous positive airway pressure (CPAP) titration in patient's sleep related breathing disorders,
- for documenting the presence of obstructive sleep apnea for patients prior to surgical interventions,
- for the assessment of treatment results in some cases,
- with a multiple sleep latency test in the evaluation of suspected narcolepsy,
- in evaluating sleep related behaviors that are injurious, and
- in certain atypical or unusual parasomnias

Medically necessary indications for polysomnography for adults include one or more of the following:

1. Witnessed apnea during sleep; OR
2. Any combination of two or more of the following (a through d):
   a. Excessive daytime sleepiness as evidenced by one or more of the following:
      - Inappropriate daytime napping (e.g., during driving, conversation, or eating);
      - Sleepiness that interferes with daily activities; (The following should be ruled out as a cause for these symptoms: poor sleep hygiene, medication, drugs, alcohol, hypothyroidism, other medical diagnoses, psychiatric, or psychological disorders, social or work schedule changes.)
      - An Epworth Sleepiness Scale score greater than 10; or
   b. Persistent or frequent socially disruptive snoring; or
   c. Obesity (BMI greater than 30 kg/m2) or hypertension; or
   d. Choking or gasping episodes associated with awakening. OR
3. Symptoms suggesting narcolepsy, e.g., sleep paralysis, hypnagogic hallucinations, cataplexy; OR
4. Violent or injurious behavior during sleep; OR
5. Other situations (if nocturnal pulse oximetry suggests nocturnal oxygen desaturation) such as
   - Unexplained right heart failure;
   - Unexplained polycythemia;
   - Presence of or increase in cardiac arrhythmias during sleep;
   - Unexplained pulmonary hypertension. OR
6. Excessive daytime sleepiness together with witnessed periodic limb movements of sleep; OR
7. Unusual or atypical parasomnias based on patient’s age, frequency, or duration of behavior; OR
8. Patients with moderate or severe congestive heart failure, stroke/TIA, coronary artery disease, or significant tachycardic or bradycardic arrhythmias who have nocturnal symptoms suggestive of a sleep related breathing disorder or otherwise suspected of having sleep apnea.

Repeat standard polysomnography for adults is considered medically necessary under the following circumstances:

1. Failure of resolution of symptoms or recurrence of symptoms during treatment; OR
2. Post-operatively following uvulopalatopharyngoplasty (UPPP) or other corrective surgeries for obstructive sleep apnea (due to the variable outcome of these surgical procedures); OR
3. Following treatment with an oral appliance for obstructive sleep apnea with an apnea hypopnea index (an AHI) or respiratory disturbance index (RDI) of >15 pre-treatment to ensure effective treatment; OR
4. To titrate CPAP following an initial polysomnography where obstructive sleep apnea was demonstrated and a split night study was not feasible; OR
5. To reevaluate the diagnosis of obstructive sleep apnea and need for continued CPAP in a patient previously diagnosed by polysomnography and currently using CPAP, if a significant weight loss has occurred since the initial study.

Not Medically Necessary:

Two Separate Night Studies
Two separate nights’ polysomnography studies, one for the diagnosis of sleep disorders and the second to titrate CPAP, are generally considered not medically necessary unless circumstances do not allow for half night or “split night” polysomnography with titration of CPAP performed in the second part of the study, (e.g., significant obstructive sleep apnea, [that is with an AHI or RDI of 20 or more with oxygen desaturations], not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep). In these cases, a second full night’s study may then be medically necessary for CPAP titration.

Repeat Standard Polysomnography
Repeat polysomnography is considered not medically necessary in the follow-up of patients with obstructive sleep apnea treated with CPAP when symptoms attributable to sleep apnea have resolved.

Polysomnography is not routinely indicated:
- to diagnose or treat restless legs syndrome,
- for the diagnosis of circadian rhythm sleep disorders,
- to establish a diagnosis of depression,
- for the following conditions existing alone in the absence of other features suggestive of obstructive sleep apnea:
  - Snoring, Obesity, Hypertension, Morning headaches, Decrease in intellectual functions, Memory loss, Frequent nighttime awakenings, Other sleep disturbances, such as insomnia (acute or chronic), night terrors, sleep walking, epilepsy where nocturnal seizures are not suspected, Common uncomplicated non-injurious parasomnias

Unattended (unsupervised) sleep studies are considered experimental / investigational.

DOCUMENTATION
Prior to performing a sleep study, the sleep laboratory’s Medical Director or physician should ascertain that the following have been completed and establish the medical necessity of the test. It is expected that the sleep laboratory will either assess the information from the ordering physician or acquire the information and document it so that medical necessity is well established or indicate why an exception is valid. Either ordering physician or sleep lab physician must sign off that these steps have been documented and evaluated prior to sleep study. This information should be kept on file for medical necessity reviews and audit purposes.

1. History and physical/sleep related symptoms, significant medical conditions, medical findings, medications, allergies, and personal habits that could affect the sleep status (i.e., alcohol consumption, psychiatric condition) should be included. Such things as a two week sleep diary may have been completed. An assessment should be made and signed by the ordering physician, and must be reviewed by the sleep laboratory or obtained by the sleep laboratory physician, in order to establish the appropriate testing and medical necessity. The history should also document an effort to screen for the possibility of depression.

2. A sleep evaluation questionnaire (mini survey), such as the Berlin questionnaire, should have been completed and assessed by the ordering physician and/or the sleep
laboratory (standard questionnaire if information is not included in #1 above).

3. A sleepiness scale, such as an Epworth scale, should have been completed. Once again, the sleep laboratory is to ascertain that the sleepiness scale fits with a clinical picture that would establish medical necessity.

4. There is an expectation that potential therapeutic options have been discussed thoroughly with the patient and potential compliance issues have been addressed. This should have been done by the ordering physician or by the sleep laboratory physician. It is also the expectation that the sleep laboratory will determine the individual education needs of the patient and will provide this education (i.e., CPAP therapy)."

- Policy Guidelines added
- Rationale section added

In Coding section:
- Removed CPT Codes: 0203T, 0204T
- Added CPT Codes: 94660, 94762, 95800, 95801
- Removed Diagnosis Codes: 327.24, 327.27, 770.81, 780.09, 780.52, 780.55, 780.56
- Added Diagnosis Codes: 327.10, 327.11, 327.13, 327.29
- Correct 347 to reflect: 347.00, 347.01, 347.10, 347.11

References section updated

01-12-2011 In Policy section:
- Removed from II B 2 the following wording as it was erroneously listed in the pediatric section of the policy, "(e.g., significant obstructive sleep apnea, [that is with an AHl or RDI of 20 or more with oxygen desaturations], not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep)."

02-25-2011 In Policy section:
- Removed the word "Titration" from I. B. and II. B. entitled CPAP Titration to read "CPAP".
- Corrected an error in Policy Guidelines #1, by removing "and an associated fall in oxygen saturation of at least 4%." from the sentence "An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort and an associated fall in oxygen saturation of at least 4%." to read "An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort."
- Corrected an error in Policy Guidelines #1 by changing "...4% oxygen desaturation." to "...3% oxygen desaturation."

08-30-2012 Description section updated

In Policy section:
- Revised policy sections from "I. Adults - 18 and over" and "II. Children - under 18" to "I. Diagnosis" and "II. Medical Management" and reformatted the indications to fall under each respectively.
- In I A 1 b c) added "(this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children)" to read "sleepiness that interferes with daily activities and is not explained by other conditions (this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children)"
- In I A 1 b 4) added "or greater than the 90th percentile for the weight/height ratio in pediatric patients," to read "Obesity, defined as a body mass index greater than 30 kg/m2 in adults or greater than the 90th percentile for the weight/height ratio in pediatric patients,"
- Moved the pediatric supervised polysomnography indications from the prior Pediatric section to become I A 1 i under the new Diagnosis section (no change in indications)
In I B 1 c added "severe" to the unattended (unsupervised) Home Sleep Studies indication of chronic pulmonary disease to read, "Severe chronic pulmonary disease"

In I B 2 added "and in pediatric patients" to read, "Unattended (unsupervised) sleep studies are considered experimental / investigational in adult patients who are considered at low to moderate risk for OSA and in pediatric patients."

In I C Repeat Supervised Polysomnography added,

1. To initiate and titrate continuous positive airway pressure (CPAP) in adult patients with clinically significant OSA defined as those patients who have:
   a. An apnea/hypopnea index (AHI) of at least 15 per hour, OR
   b. An AHI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

   Note:
   - In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 is considered severe.
   - A split-night study, in which severe OSA is documented during the first portion of the study using polysomnography, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines for criteria to perform a split-night study).

   - Removed from I E "[that is with an AHI or RDI of 20 or more with oxygen desaturations]," to read "e.g., significant obstructive sleep apnea, [that is with an AHI or RDI of 20 or more with oxygen desaturations], not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep]."

   - Added the new medically necessary indication of "I I B Bilevel positive airway pressure or auto-adjusting CPAP may be considered medically necessary in patients with clinically significant OSA AND who have failed a prior trial of CPAP or for whom BiPAP is found to be more effective in the sleep lab."

   - Revised Intraoral Appliances from "Intraoral appliances* may be considered medically necessary in patients with clinically significant OSA, as defined in Policy Guidelines. *Intraoral appliances include either tongue-retaining devices or mandibular advancing/positioning devices." to "Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in patients with clinically significant OSA under the following conditions:
     1. OSA, defined by an apnea/hypopnea index (AHI) of at least 15 per hour or an AHI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension, AND
     2. The device is prescribed by a treating physician, AND
     3. The device is custom-fitted by qualified dental personnel. AND

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

   - Added the new experimental / investigational indication of "A nasal expiratory positive airway pressure (EPAP) device is considered experimental / investigational."

Rationale section updated

In Coding section:
- Add HCPCS Code: E1399

References updated

01-01-2013

In Coding section:
- Added CPT codes: 95782, 95783 (effective 01-01-2013)
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**REFERENCES**


*Contains Public Information*


