Medical Policy

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Title: Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

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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.

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Background

In patients with obstructive sleep apnea (OSA), the normal pharyngeal narrowing is accentuated by anatomic factors, such as a short, wide neck, elongated palate and uvula, or large tonsillar pillars with redundant lateral pharyngeal wall mucosa. Furthermore, OSA may be associated with a wide variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. In addition, OSA is associated with obesity. Obstruction anywhere along the upper airway can result in apnea. Therefore, OSA is associated with a heterogeneous group of anatomic variants producing obstruction.

The hallmark symptom of OSA is excessive daytime sleepiness; the hallmark clinical sign 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. Sleep fragmentation associated with repeated arousal during sleep can lead to impairment of daytime activity. For example, adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, i.e., cars, trucks, or heavy equipment. OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects 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.

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," or "RERAs"). The resistance to airflow is typically subtle and does not result in scorable apneic or hypopneic events. RERAs are scored if there is a sequence of breaths lasting at least 10 seconds characterized by increasing respiratory effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea or hypopnea. Snoring may not be a feature of UARS. However, it does result in increasingly negative intrathoracic pressure during inspiration, which can be measured using an esophageal manometer as an adjunct to a polysomnogram. Therefore, this diagnosis rests on polysomnographic documentation of greater than 10 EEG arousals per hour of sleep correlated with episodes of greater than normal negative intrathoracic pressures. RERAs can also be detected absent manometry during polysomnography. It has been proposed that UARS is a distinct syndrome from OSA that may be considered a disease of arousal. In the absence of intrathoracic pressure monitoring, a positive response to continuous positive airway pressure (CPAP) has also been used to support the diagnosis.

In adults, OSA is often suspected on the basis of the clinical history and physical appearance; i.e., an overweight individual with a wide neck. The most common symptoms are snoring, excessive daytime sleepiness, and hypertension. Excessive daytime sleepiness may be subjective and may be assessed by questionnaires such as the Epworth Sleepiness Scale (ESS), a short self-administered questionnaire that asks patients, "How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?"

1. Sitting and reading

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

The patient rates his or her likelihood of falling asleep in these 8 different situations as: 0 (would never doze), 1 (slight chance of dozing), 2 (moderate chance of dozing), or 3 (high chance of dozing). The maximum score is 24, and a score of 10 or below is considered normal.

Daytime sleepiness may also be measured objectively with tests such as the multiple sleep latency test or the maintenance of wakefulness test. The multiple sleep latency test measures how quickly the patient falls asleep when instructed to relax in a quiet and dimly lit room, and the maintenance of wakefulness test measures sleep latency when the patient is instructed to attempt to remain awake in an unstimulating environment. These tests are not considered necessary to evaluate sleep apnea, but the multiple sleep latency test may be used when symptoms, including excessive daytime sleepiness, suggest narcolepsy.

Daytime sleepiness is uncommon in young children with OSA. Symptoms in children may include habitual snoring (often with intermittent pauses, snorts, or gasps), disturbed sleep, and daytime neurobehavioral problems. OSA can occur in children of all ages, from neonates to adolescents. Risk factors include adenotonsillar hypertrophy, obesity, craniofacial anomalies, and neuromuscular disorders. In otherwise healthy children, OSA is usually associated with adenotonsillar hypertrophy and/or obesity. The first-line treatment for pediatric OSA is adenotonsillectomy.

The final diagnosis of OSA rests on a combination of clinical evaluation and objective criteria to identify those levels of obstruction that are considered to be clinically significant. The gold standard diagnostic test for sleep disorders is considered a polysomnogram, performed in a sleep laboratory. (1) A standard polysomnogram, supervised by a sleep lab technician, typically includes:

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

Additional parameters of sleep that are typically measured during in-lab polysomnography include:

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

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

Typically, the evaluation of OSA includes sleep staging to assess arousals from sleep and determination of the frequency of apneas and hypopneas from channels measuring oxygen desaturation, respiratory airflow, and respiratory effort. In adults, an obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort. Obstructive hypopnea is an equal to or greater than 30% reduction in airflow, with an associated fall in oxygen saturation (at least 4%) or arousal. (An accepted alternative definition of hypopnea is an equal to or greater than 50% reduction in airflow with equal to or greater than 3% desaturation). 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 (e.g., 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 syndrome 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. Hypopneas are scored by a 50% or greater drop in nasal airflow and either an equal to or greater than 3% decrease in oxygen saturation or an associated arousal. In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 or greater is 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. Sources of measurement error with polysomnography include data loss, artifact, event recognition errors, measurement errors, use of different types of leads, and night-to-night variability.

It is estimated that about 7% of adults have moderate or severe OSA, and 20% have at least mild OSA and that the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease. (2) In light of the limited capacity of sleep laboratories, a variety of devices have been developed specifically to evaluate OSA at home. These range from portable full polysomnography systems to single channel oximeters. Available devices evaluate different parameters, which may include oximetry, respiratory and cardiac monitoring, and sleep/wake activity, but the majority of portable monitors do not record EEG. It has been proposed that unattended studies with portable monitoring devices may improve the diagnosis and treatment of patients with OSA, although the limited number of

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channels in comparison with full polysomnographic recording may decrease the capability for differential diagnosis or detection of comorbid conditions.

Medical management of OSA includes weight loss, oral appliances, and various types of positive pressure therapy (i.e., fixed CPAP, bilevel positive airway pressure [BiPAP], or auto-adjusting CPAP). CPAP involves the administration of air, usually through the nose, by an external device at a fixed pressure to maintain the patency of the upper airway. Bilevel positive airway pressure is similar to CPAP, but these devices are capable of generating 2 adjustable pressure levels. Auto-adjusting CPAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been hypothesized that both bilevel positive airway pressure and auto-adjusting CPAP 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. A number of oral appliances have received marketing clearance through the U.S. Food and Drug Administration’s 510(k) pathway (product code LQZ) for the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™, LambergSleepWell-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. In 2010, a nasal expiratory resistance valve (PROVENT, Ventus Medical) received marketing clearance 510(K) for the treatment of OSA. PROVENT is a single use device containing valves that are inserted into the nostrils and secured with adhesive.

PSG may also be performed in patients with symptoms suggestive of narcolepsy (excessive sleepiness, cataplexy, sleep paralysis, and sleep-related hallucinations), unrefreshing sleep with daytime fatigue/sleepiness but without snoring or witnessed apneas, obesity hypoventilation syndrome (obesitywith poor breathing, leading to hypoxiaand hypercarbia), parasomnias, periodic limb movements during sleep, sleep-related seizure disorder, and neuromuscular disorders with sleep-related symptoms. The American Academy for Sleep Medicine (AASM) has published guidelines for polysomnography and related procedures for these indications. (1)

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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

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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

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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.

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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.

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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 mild-

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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.

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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.

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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.

<u>Utilization</u>

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

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RATIONALE

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 obstructive sleep apnea. (5, 6) This policy focuses, therefore, on patient selection criteria for polysomnography (PSG), or sleep study, and the use of home sleep studies as an alternative to a supervised laboratory study. In addition, the use of expiratory positive airway pressure (EPAP), auto-adjusting CPAP (APAP) or bilevel positive airway pressure (BiPAP) in patients with OSA is reviewed.

Definition of Clinically Significant OSA: The original rationale for the diagnosis and treatment of OSA was based on epidemiologic studies that suggested increased mortality in patients with an apneic index greater than 20. However, considering that an apneic/hypopnea index (AHI) of 5 is considered normal, there is obviously a great range of severity of OSA, ranging from those with only snoring as a complication to those with associated severe excessive daytime sleepiness, hypertension, or cardiac arrhythmias. If OSA is considered mild to moderate and snoring is the only manifestation, an intervention would be considered not medically necessary. For example, pronounced snoring may be considered predominantly a social annoyance to the patient's bed partner with no impact on the patient him/herself.

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. (7) The CER found strong evidence that an AHI greater than 30 events/hour is an independent predictor of all-cause mortality, with low or insufficient evidence for an association between AHI and other clinical outcomes. The CER found moderate evidence that type 3 and type 4 monitors may have the ability to accurately predict AHI suggestive of OSA and that type 3 monitors perform better than type 4 monitors at AHI cutoffs of 5, 10, and 15 events per hour. Despite no or weak evidence for an effect of CPAP on clinical outcomes, given the large magnitude of effect on the intermediate outcomes of AHI, Epworth Sleepiness Scale (ESS), and arousal index, the strength of evidence that CPAP is an effective treatment to alleviate sleep apnea signs and symptoms was rated moderate. The strength of the evidence that mandibular advancement devices improve sleep apnea signs and symptoms was rated moderate, and there was moderate evidence that CPAP is superior to mandibular advancement devices in improving sleep study measures.

Attended PSG has been considered to be the gold standard in the diagnosis and treatment of OSA. In 2007, AHRQ conducted a technology assessment on portable monitoring for the Medicare Evidence Development and Coverage Committee (MedCAC). (8)

The report concluded:

- Baseline AHI (or other indices obtained from sleep studies) is only modestly associated with response to CPAP or CPAP use among people with high (pre-test) probability for obstructive sleep apnea-hypopnea syndrome. None of the eligible studies assessed hard clinical outcomes (i.e., mortality, myocardial infarctions, strokes, and similar outcomes).
- Based on limited data, type 2 monitors may identify AHI suggestive of obstructive sleep apnea-hypopnea syndrome with high positive likelihood ratios (>10) and low negative likelihood ratios (<0.1) both when the portable monitors were studied in the sleep laboratory and at home.

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- Type 3 monitors may have the ability to predict AHI suggestive of obstructive sleep apnea-hypopnea syndrome with high positive likelihood ratios and low negative likelihood ratios compared to laboratory-based PSG, especially when manual scoring is used. The ability of type 3 monitors to predict AHI suggestive of obstructive sleep apnea-hypopnea syndrome appears to be better in studies conducted in the specialized sleep unit compared to studies in the home setting.
- Studies of type 4 monitors that record at least three bioparameters showed high positive likelihood ratios and low negative likelihood ratios. Studies of type 4 monitors that record one or two bioparameters also had high positive likelihood ratios and low negative likelihood ratios, at least for selected sensitivity and specificity pairs from receiver operating characteristic (ROC) curve analyses. Similarly to type 3 monitors, the ability of type 4 monitors to predict AHI suggestive of obstructive sleep apnea-hypopnea syndrome appears to be better in studies conducted in specialized sleep units.
- Patients older than the studied subjects (the median average age was approximately 50 years in the analyzed studies) may have more comorbidities that affect sleep (i.e., non-obstructive sleep apnea-hypopnea syndrome conditions such as cardiac insufficiency; chronic obstructive pulmonary disease; obesity hypoventilation syndrome; or periodic limb movements in sleep and restless leg syndrome). These conditions may be misdiagnosed if the sleep monitors do not record channels necessary for differential diagnosis from obstructive sleep apnea-hypopnea syndrome.
- For studies in the home setting, there are no direct data on whether and to what extent technologist support and patient education affect the comparison of portable monitors with facility-based PSG.
- Overall, manual scoring or manual editing of automated scoring seems to have better agreement with facility-based PSG. The automated scoring algorithms may vary across different monitors, or even with the specific software version or settings. Thus, their ability to recognize respiratory events may differ.
- Signal loss was more often observed in home studies, and 1 study associated discrepancies in the AHI measurement with poor quality airflow signals in the unattended home-based recordings.

In 2008, the Centers for Medicare and Medicaid Services (CMS) implemented a national coverage decision allowing an initial 12-week period of CPAP based on a clinical evaluation and a positive sleep test performed with either an attended PSG performed in a sleep laboratory or an unattended home sleep test with a device that measures at least three channels. (9) Previously, coverage for CPAP required determination of AHI from attended PSG in a sleep laboratory, effectively establishing PSG-defined AHI as the only acceptable measure of OSA. As indicated in the AHRQ report, there is a poor correlation between AHI and daytime sleepiness, as well as between improvement in AHI and improvement of symptoms with CPAP usage. In addition, effectiveness of CPAP is affected by tolerance to the device (mask and airway pressure) and ultimately by compliance with treatment. These issues raise the question of whether PSG-defined AHI and manual titration of CPAP should remain the only means for diagnosis and treatment of OSA. Therefore, this policy evaluates the literature on the clinical utility of portable monitoring devices to identify patients with a high likelihood of benefit from treatment, without increasing potential harm from misdiagnosis.

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Mulgrew et al. published a randomized validation study of the diagnosis and management of OSA with a single channel monitor followed by APAP. (10) They developed a diagnostic algorithm (Epworth Sleepiness Scale [ESS] score greater than 10, Sleep Apnea Clinical Score of 15 or greater, and a respiratory disturbance index [RDI] of 15 or greater on overnight oximetry) 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. Home monitoring consisted of autotitration for 1 week, followed by download and assessment of efficacy data for the week (i.e., CPAP, mask leak, residual respiratory events, and use) and determination of the pressure for CPAP by the study physician. A second assessment of efficacy data was conducted for a week of CPAP use, and the pressure setting was adjusted by the CPAP coordinator in conjunction with the study physician. After 3 months of CPAP use, the subjects returned to the laboratory for PSG (with CPAP); no difference was observed between lab-PSG and home-managed patients in any of the outcome measures (median AHI of 3.2 vs. 2.5, median ESS of 5.0 vs. 5.0, and Sleep Apnea Quality-of-Life Index of 5.5 vs. 5.8, all respectively). Another study assessed the clinical utility of home oximetry in comparison with PSG by measuring the accuracy with which sleep physicians could predict which patients would benefit from treatment of OSA. (11) The primary outcome measure was the change in sleep apnea-specific quality of life after treatment. Subjects were randomly selected from a pool of referred patients; 307 were randomized, and 288 began a trial of CPAP. An additional 51 patients (18%) quit before the end of the 4-week CPAP trial; 31 indicated that they had trouble sleeping with CPAP, 3 removed the mask in their sleep, and 2 had nasal or sinus congestion. Overall, physicians predicted success in 50% of patients and 42% met the criterion for improvement. Outcomes of treatment were similar in the 2 groups, with improvements in ESS scores of 3.4 for home monitoring and 4.0 for PSG. The ability of physicians to predict the outcome of treatment was similar for the 2 methods. Five cases (2%) required PSG for diagnosis of other nonrespiratory sleep disorders (narcolepsy, periodic leg movements, and idiopathic hypersomnolence).

Skomro et al. conducted a randomized trial (102 patients) of home testing followed by 1 week of APAP, compared with in-laboratory PSG followed by CPAP titration. (12) The study included adult patients with suspected OSA who had been referred to participating sleep medicine physicians at a tertiary sleep disorders clinic. Patients were included in the study if they had at least 2 symptoms of OSA (ESS >10, witnessed apneas, or snoring). The average ESS at baseline was 12.5. Exclusion criteria were respiratory or heart failure, clinical features of another sleep disorder, use of hypnotics, upper airway surgery, CPAP or oxygen therapy, pregnancy, or a safety-sensitive occupation. For home testing, a type 3 monitor was used that measured airflow, respiratory effort, oxygen saturation, heart rate, and body position, and home studies with technical failures or less than 4 hours of recording were repeated (17% of patients). After completion of testing and before application of APAP/CPAP, the subjects also underwent the other sleep test (home or laboratory). All studies were scored manually by a technician and reviewed by a sleep medicine physician, and subjects and investigators were blinded to the results of the second test. After sleep testing, 89 subjects received a diagnosis of OSA and were prescribed CPAP; 10 of those patients rejected CPAP treatment. In the home monitoring group, the proportion of subjects with an AHI greater than 30 was significantly lower, and the APAP-derived CPAP pressure was significantly higher than the manually-titrated CPAP pressure from the laboratory study. After 4 weeks of therapy, there were no significant differences between laboratory and home monitoring groups on any of the outcome measures; daytime sleepiness measured by the ESS (6.4 vs. 6.5), sleep quality measured by the Pittsburgh Sleep Quality Index

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(5.4 vs. 6.2), quality of life (4.5 vs. 4.6), Short-Form 36 (SF-36) Health Survey (62.2 vs. 64.1), blood pressure (129/84 vs. 125/81), or CPAP adherence (5.6 h/night vs. 5.4 h/night – all respectively).

Senn and colleagues assessed whether an empiric approach, using only a 2-week trial of APAP, could be effective for the diagnosis of OSA. (13) 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 of 13.6). Exclusion criteria were contraindications to CPAP or APAP (heart failure, lung disease, obesity, hypoventilation syndrome), previous diagnosis or treatments of a sleep disorder, or a diagnosis of an internal medical, neurologic, or psychiatric disorder explaining the symptoms. 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.

Garcia-Diaz and colleagues assessed the sensitivity and specificity of home respiratory polygraphy and actigraphy to diagnose OSA in relation to laboratory PSG. (14) The cohort consisted of 65 consecutive patients referred to the sleep laboratory for PSG because of suspected OSA. Using an AHI cutoff of 15 or more, 2 independent evaluators were found to identify PSG-defined OSA in 90% to 92% of the patients (sensitivity of 84–88% and specificity of 97%). Analysis of data from the Swiss respiratory polygraphy registry found that in patients selected for portable monitoring (based on high clinical suspicion of OSA by licensed pulmonary physicians by a combination of hypersomnia, snoring, or observed apneas), confirmation or exclusion of sleep disordered breathing was possible in 96% of the 8,865 diagnostic sleep studies. (15) From these type 3 studies (four channels including airflow and respiratory movement, heart rate or electrocardiogram [ECG], and oxygen saturation), 3.5% were not conclusive and required additional PSG.

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. (16) (See Medicare National Coverage, below, along with the Policy Guidelines section regarding new category III codes for devices with this configuration of sensors.) A literature review of this technology in September 2009 identified a review of use of peripheral arterial tone for detecting sleep disordered breathing. (17) This review includes the critical evaluation of a number of studies comparing the Watch-PAT™ with laboratory-based PSG. Relevant studies that included appropriate study populations (patients referred for evaluation of OSA or following CPAP treatment) are described.

Berry and colleagues 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. (18) Patients were screened with a detailed sleep and medical history questionnaire including an ESS. To be included in the study, patients had to have an ESS score of 12 or greater and the presence of at least 2 of the following: loud habitual snoring, witnessed apnea/gasping, or treatment for hypertension. Patients on alpha-blockers or not in sinus rhythm were excluded due to the type of portable monitoring device used

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(Watch-PAT™ 100), which records sympathetic changes in peripheral arterial tone, heart rate, pulse oximetry, and actigraphy. Also excluded were patients with moderate to severe heart failure, use of nocturnal oxygen, chronic obstructive pulmonary disease, awake hypercapnia, neuromuscular disease, cataplexy, restless leg syndrome, use of narcotics, psychiatric disorder, shift work, or a prior diagnostic study or treatment. Of the 53 patients randomized to PSG, 6 (11%) did not have PSG-defined OSA; 43 of 49 patients (88%) with CPAP titrations started on CPAP. In the portable monitoring arm, 4 of 53 patients (8%) were found not to have OSA. A physician affiliated with the sleep research laboratory reviewed the tracings for technical quality to determine if the events were correctly identified by the analysis program. Four studies (8%) were repeated due to technical failure or insufficient sleep. Patients with negative studies were then crossed over, which identified an additional 2 patients from the PSG arm as having OSA and 1 patient from the PM-APAP arm as having OSA. These patients (total of 50) had at least 1 APAP titration, 45 of the 50 (90%) had an adequate APAP titration and accepted treatment. Adherence was similar in the two groups, with 91% of patients in the PSG arm and 89% of patients in the PM-APAP arm continuing treatment at 6 weeks. Treatment outcomes were similar in the two groups, with a 7-point improvement in ESS score, 3-point improvement in the Functional Outcomes of Sleep Questionnaire, 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. (19) Exclusion criteria for the study were diagnosis of periodic leg movement disorder, RDI less than 20 on diagnostic PSG, history of peripheral vascular disease, peripheral neuropathy, nonsinus cardiac rhythm, permanent pacemaker, severe lung disease, bilateral cervical or thoracic sympathectomy, finger deformity precluding sensor application, and use of alpha-adrenergic blockers. Compared to concurrently recorded PSG, the area under the curve (AUC) from receiver-operator characteristic (ROC) analysis for RDI greater than 15 was 0.95 (85% sensitivity and 90% specificity). Specificity decreased dramatically at lower cutoffs (67% for RDI >10 and 47% for an 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). (20) (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 and colleagues raised concern about the specificity of this device in an independently conducted small study of 21 patients with suspected sleep apnea. (21) 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 authors concluded that the specificity of the Watch-PAT is limited. The long list of exclusion criteria in company-sponsored trials also raises questions 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 and colleagues noted other potential disadvantages of the Watch-PAT, including the inability to differentiate between the type of respiratory event (e.g., obstructive, central, mixed, or hypopnea) or to identify body position, and susceptibility to artifact from arrhythmias. (22) In this study, 28% of the cases did not achieve concordance (defined as both Watch-PAT and PSG RDI of >40 per hour, or within 10 events per hour in patients with an RDI <40 per hour). 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

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conventionally used for in-laboratory PSG. (23) At this time, evidence is insufficient to support a change in the sensors required for portable monitoring.

BiPAP and APAP

A 1995 study by Reeves-Hoche et al. randomized patients with OSA to receive either CPAP or BiPAP. (24) 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. 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. (7) Evidence-based guidelines from the AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals. (25-28) As indicated in the 2011 AHRQ CER, increased compliance with APAP devices has not been well-documented in clinical trials. (29-31) Thus, the issues associated with APAP are similar to BiPAP; i.e., APAP may be considered medically necessary in patients who have failed a prior trial of CPAP. In addition to the studies (described previously) that used unattended APAP devices to titrate CPAP pressure, 2007 AASM practice parameters on autotitration identified 5 randomized trials supporting the use of unattended APAP to determine a fixed CPAP treatment pressure for patients with moderate to severe OSA without significant comorbidities affecting respiration. (28) This new practice parameter was considered an option (uncertain clinical use), with automatic titration or treatment requiring close clinical follow-up (standard). The practice parameters for the use of APAP issued by the AASM point out that results may vary with different APAP devices based on different underlying technologies, and thus caution must be exercised in selecting a particular device for use. (25-28)

Nasal Expiratory Positive Airway Pressure (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. (32) Two-hundred and 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 and -10.1% at 3 months). Over 3 months, the decrease in ESS was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1 point difference in the ESS is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of 5 or more per hour on the device-off PSG night. The oxygenation results (oxygenation desaturation index and % of total sleep time with SpO2 <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduced to less than 10 (if device-off AHI was 10 or more), was greater in the EPAP group at 1 week (62% vs. 27.2%) and 3 months (50.7% vs. 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing the study due to adverse events. Overall, the validity of these results is limited by the high dropout rate, and the clinical significance of the results is uncertain.

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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. (33) 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.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers

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

2009

In response to requests, input was received from 5 physician specialty societies (6 reviewers) and 3 academic medical centers while this policy was under review in 2009. Professional society guidelines and position statements were also reviewed. In general, the input supported the use of PSG, portable sleep monitoring tests, multiple sleep latency test, and CPAP for adults as described in the policy. The March 2009 update includes the reviewer's recommendations for clarifications and modifications to the policy statements.

2010

In response to requests, input was received from 1 physician specialty society and 6 academic medical centers (8 reviewers) for the 2010 policy update. The input focused on the sensors required for unattended home sleep studies and on diagnosis and treatment of OSA in children. In general, the reviewers supported the requirement that home monitors measure four 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.

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Summary

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

- Portable monitoring should only 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 four channels of recording, including arterial oxygen saturation, airflow and respiratory effort, has a high positive predictive value for OSA and can be used as the basis for a CPAP 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 one industry-sponsored randomized controlled trial. The main finding of this study was a decrease in AHI with minor impact on oxygenation and the ESS. Evidence at this time is insufficient to permit conclusions regarding the effect of this technology on health outcomes.

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 AASM) published practice parameters for PSG and related procedures; these were most recently updated in 2005. (1, 34) The guidelines suggested that patients had a 70% likelihood of having an AHI index of at least 10 if all of the following were present: habitual snoring, excessive daytime sleepiness, a body mass index greater than 35, and observed apneas. In 2005, full-night PSG was recommended for the diagnosis of sleep-related breathing disorders and for PAP titration in patients with an RDI of at least 15 per hour, or with an RDI of at least 5 per hour in a patient with excessive daytime sleepiness. (1) For patients in the high-pretest-probability stratification group, an attended cardiorespiratory sleep study (type 3 with respiratory effort, airflow, arterial oxygen saturation, and electrocardiogram [ECG] or heart rate) was considered an acceptable alternative to full-night PSG, provided that repeat testing with full-night PSG was permitted for symptomatic patients who had a negative cardiorespiratory sleep study finding. In their 2005 Guidelines, AASM stated that data were

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insufficient to support unattended portable sleep studies, but they might be considered acceptable when the patient has severe symptoms requiring immediate treatment and PSG is not available, the patient cannot be studied in a sleep laboratory (i.e., nonambulatory), or for follow-up studies to evaluate response to therapy. (1) The document further stated that, in these patients, a sleep study may be an acceptable alternative to PSG. However, a sleep study may only "rule in" disease, and PSG should be available for patients with false-negative sleep study results. An additional recommendation of note is that sleep studies were not recommended in patients with comorbid conditions or secondary sleep complaints. Most of the literature reviewed specifically excluded patients with comorbid conditions. A cardiorespiratory sleep study without EEG recording was not recommended for CPAP titration, as sleep staging was considered necessary. Finally, practice parameters stated that a multiple sleep latency test is not routinely indicated for most patients with sleep-related breathing disorders.

Portable monitoring (PM) devices were addressed by a joint project of the AASM, the American Thoracic Society, and the American College of Chest Physicians in 2003. (35, 36) In 2007 the 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. (23)

Evidence-based guidelines on BiPAP, APAP, and dental appliances have been published by the AASM. (25-28) 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 present. (37) 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 (e.g., obesity hypoventilation syndrome), patients who do not snore, and patients who have central sleep apnea syndromes. (28) 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 re-evaluation 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.

The AASM published evidence-based guidelines for respiratory indications for polysomnography in children in 2011. (38) "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

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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 Otolaryngology – Head and Neck Surgery published clinical practice guidelines on PSG for sleep-disordered breathing prior to tonsillectomy in children in 2011. (39) 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 of 10 or more, oxygen saturation nadir less than 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 Academy of Pediatrics (AAP) published a 2002 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; complex high-risk patients should be referred to a specialist. (40) The AAP guidelines stated that diagnostic evaluation is useful in discriminating between primary snoring and OSA; although the gold standard is overnight PSG, other diagnostic tests such as PSG of daytime naps or home oximetry may be useful if results are positive. Adenotonsillectomy is the first line of treatment for most children, and CPAP is an option for those who are not candidates for surgery or do not respond to surgery; patients should be reevaluated post-operatively to determine whether additional treatment is required. No updates of this guideline have been identified.

In 2008 the United Kingdom's National Institute for Health and Clinical Excellence (NICE) issued guidance on CPAP treatment of OSA, based on a review of the literature and expert opinion. (41) 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 5–14 in a sleep study, moderate when the AHI is 15–30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

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- 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.

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)

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

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G0400 Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels

Attended Studies
CPT Codes: 95807, 95808, 95810, 95811.

Unattended Study
- Note that CPT code 95806 is identical to 95807 except that the study is not monitored.
- Effective January 1, 2011, there are additional CPT codes for unattended sleep studies: 95800, 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 one HCPCS code identifying a CPAP device, E0601, and 2 HCPCS codes for bilevel positive airway pressure devices, E0470 and E0471. The HCPCS codes do not distinguish among fixed CPAP or bilevel positive airway pressure devices and auto-adjusting CPAP devices.
- In 2008, Medicare created some G codes to facilitate their national coverage decision: G0398, G0399, G0400.

DIAGNOSIS

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

Covered Diagnosis

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

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REVISIONS

01-01-2011	In Title: ▪ Policy title changed from "Polysomnography and Sleep Studies" to "Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome"
	Description section updated
	In policy section: ▪ 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

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	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: <u>Two Separate Night Studies</u> 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. <u>Repeat Standard Polysomnography</u> 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: oSnoring oObesity oHypertension oMorning headaches oDecrease in intellectual functions

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	oMemory loss oFrequent nighttime awakenings oOther sleep disturbances, such as insomnia (acute or chronic), night terrors, sleep walking, epilepsy where nocturnal seizures are not suspected oCommon 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 ▪ Added HCPCS Codes: A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, E0470, E0471, E0485, E0486, E0561,E0562, E0601

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	▪ 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 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)."
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:

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	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 "II 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.” ▪ Policy Guidelines updated
	Rationale section updated
	In Coding section: ▪ Add HCPCS Code: E1399
	References updated

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01-01-2013	In Coding section: ▪ Added CPT codes: 95782, 95783 (effective 01-01-2013) ▪ Revised nomenclature on CPT code: 95808, 95810, 95811 (effective 01-01-2013)

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