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Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328
Original Effective Date: 07/27/2012
Current Effective Date: 03/19/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome *is addressed separately in medical policy 00329.*

Note: Actigraphy *is addressed separately in medical policy 00330.*

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Diagnosis
Based on review of available data, the Company may consider supervised polysomnography (PSG) performed in a sleep laboratory may as a diagnostic test in patients with any of the following to be **eligible for coverage**:

- Observed apneas during sleep; or
- A combination of at least two of the following:
    - Excessive daytime sleepiness evidenced by an Epworth Sleepiness Scale (ESS) greater than 10, inappropriate daytime napping (e.g., during driving, conversation, or eating), or sleepiness that interferes with daily activities and is not explained by other conditions, (this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children);
    - Habitual snoring, or gasping/choking episodes associated with awakenings;
    - Unexplained hypertension;
    - Obesity, defined as a body mass index greater than 35 kg/m2 in adults or greater than the 90^{th} percentile for the weight/height ratio in pediatric patients;
    - Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease; or
- 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.

Based on review of available data, the Company may consider a single unattended (unsupervised) home sleep studies with a minimum of 4 recording channels (including oxygen saturation, respiratory movement, airflow, and EKG or heart rate) in adult patients who are at high risk for obstructive sleep apnea (OSA) and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including the following to be **eligible for coverage**:

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- Central sleep apnea
- Congestive heart failure
- Chronic pulmonary disease
- Obesity hypoventilation syndrome
- Narcolepsy
- Periodic limb movements in sleep
- Restless leg syndrome

Based on review of available data, the Company may consider a repeated supervised polysomnography (PSG) performed in a sleep laboratory under the following circumstances to be **eligible for coverage**:

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

  Notes:
  - 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 obstructive sleep apnea (OSA) is documented during the first portion of the study using polysomnography (PSG), followed by continuous positive airway pressure (CPAP) during the second portion of the study, can eliminate the need for a second study to titrate continuous positive airway pressure (CPAP) (see Policy Guidelines for criteria to perform a split-night study).
  - Respiratory disturbance index may be used in place of apnea/hypopnea index (AHI) in unattended sleep studies.
- Failure of resolution of symptoms or recurrence of symptoms during treatment; or
- To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices; or
- To re-evaluate the diagnosis of obstructive sleep apnea (OSA) and need for continued continuous positive airway pressure (CPAP), e.g., if there is a significant change in weight or change in symptoms suggesting that continuous positive airway pressure (CPAP) should be retitrated 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.

Based on review of available data, the Company may consider repeated unattended (unsupervised) home sleep studies with a minimum of four recording channels (including oxygen saturation, respiratory movement, airflow, and EKG/heart rate) in adult patients under the following circumstances to be **eligible for coverage**:

- To assess efficacy of surgery or oral appliances/devices; or

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- To re-evaluate the diagnosis of obstructive sleep apnea (OSA) and need for continued continuous positive airway pressure (CPAP), e.g., if there is a significant change in weight or change in symptoms suggesting that continuous positive airway pressures (CPAPs) should be retitrated or possibly discontinued.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers multiple sleep latency testing in the diagnosis of obstructive sleep apnea (OSA), except to exclude or confirm narcolepsy or other hypersomnia syndromes, in the diagnostic workup of obstructive sleep apnea (OSA) syndrome to be **not medically necessary**.**

Based on review of available data, the Company considers multiple consecutive nights of supervised or unattended (unsupervised) sleep studies that do not meet the above criteria for repeat studies to be **not medically necessary.**

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers attended (supervised) laboratory sleep studies for any other indication not listed above to be **investigational.***

Based on review of available data, the Company considers unattended (unsupervised) sleep studies for the following indications to be **investigational.***
- Adult patients who are considered at low to moderate risk for obstructive sleep apnea (OSA); or
- Pediatric patients (i.e., younger than 18 years of age); or
- Without a minimum of 4 recording channels; or
- All other indications not listed above.

Based on review of available data, the Company considers the use of an abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies to be **investigational**.

Medical Management
Based on review of available data, the Company may consider continuous positive airway pressure (CPAP) in adult or pediatric patients with clinically significant obstructive sleep apnea (OSA) to be **eligible for coverage**.

Based on review of available data, the Company may consider auto-adjusting continuous positive airway pressure (CPAP) during a 4-week trial to initiate and titrate continuous positive airway pressure (CPAP) in adult patients with clinically significant obstructive sleep apnea (OSA) to be **eligible for coverage**.

Based on review of available data, the Company may consider bilevel positive airway pressure or auto-adjusting continuous positive airway pressure (CPAP) in patients with clinically significant obstructive sleep

apnea (OSA) and who have failed a prior trial of continuous positive airway pressure (CPAP) or for whom BiPAP is found to be more effective in the sleep lab to be **eligible for coverage**.

Based on review of available data, the Company may consider intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) in patients with clinically significant obstructive sleep apnea (OSA) under the following conditions to be **eligible for coverage:**

- Obstructive sleep apnea (OSA), defined by an apnea/hypopnea index (AHI) of at least 15 per hour or an apnea/hypopnea index (AHI) of at least five events per hour in a patient with excessive daytime sleepiness or unexplained hypertension, and
- A trial with continuous positive airway pressure (CPAP) has failed or is contraindicated, and
- The device is prescribed by a treating physician, and
- The device is custom-fitted by qualified dental personnel, and
- There is absence of temporomandibular dysfunction or periodontal disease

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

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers a nasal expiratory positive airway pressure (EPAP) and oral pressure therapy devices to be **investigational**.*

Based on review of available data, the Company considers any other use of devices for the diagnosis and management of obstructive sleep apnea (OSA) not listed in the coverage section to be **investigational**.*

Background/Overview

Obstructive sleep apnea syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. Obstructive sleep apnea is typically diagnosed by overnight monitoring with PSG. Medical management of OSA may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep.

In patients with 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. Obstructive sleep apnea 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 scoreable 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 PSG. 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 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 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
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. Obstructive sleep apnea 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. 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 PSG include:

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

The first 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.

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

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

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Polysomnography may also be performed in patients with symptoms suggestive of narcolepsy (excessive sleepiness, cataplexy, sleep paralysis, and sleep-related hallucinations), unrefreshing sleep with daytime fatigue/sleepiness but without snoring or witnessed apneas, obesity hypoventilation syndrome (obesity with poor breathing, leading to 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 PSG and related procedures for these indications.

Policy Guidelines
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). 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. 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.

The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness, and an 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 is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

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

Although not an exclusive list, patients with all four 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

If no bed partner is available to report snoring or observed apneas, other signs and symptoms suggestive of OSA, (e.g., age of the patient, male gender, thick neck, or craniofacial or upper airway soft tissue abnormalities) may be considered. Objective clinical prediction rules are being developed; however, at the present time, risk assessment is based on clinical judgment. Overnight oximetry has been used by some

sleep specialists as a component of the risk assessment but is not adequate for the diagnosis of OSA. Therefore, a follow-up PSG or home sleep study would still be required to confirm or exclude a diagnosis of OSA.

American Academy for Sleep Medicine (AASM) Practice Parameters indicate that a split-night study (initial diagnostic PSG followed by CPAP titration during PSG on the same night) is an alternative to one full night of diagnostic PSG followed by a second night of titration if the following four criteria are met:

a. An AHI of at least 40 is documented during a minimum of two 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.
b. CPAP titration is carried out for more than three hours (because respiratory events can worsen as the night progresses).
c. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM (NREM) sleep, including REM sleep with the patient in the supine position.
d. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder (SRBD) is confirmed, but criteria b and c are not met.

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

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Medical management of OSA includes weight loss, oral appliances, and various types of positive pressure therapy (i.e., fixed CPAP, BiPAP, or auto-adjusting CPAP). Continuous positive airway pressure 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 two 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 BiPAP 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. FDA'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.

Centers for Medicare and Medicaid Services (CMS)
The use of CPAP devices are covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adults with OSA if either of the following criteria using the AHI or RDI are met:

- AHI or RDI $\geq$ 15 events per hour, or
- AHI or RDI between 5 and 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

The AHI or RDI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of two hours of sleep using actual recorded number of hours of sleep (i.e., the AHI or RDI may not be extrapolated or projected). Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

In 2001, the CMS (formerly Health Care Financing Administration), published a decision memorandum for CPAP that addressed the issue of how to define moderate to severe OSA as a guide to a coverage policy

for CPAP. This review of the literature suggested that there is a risk of hypertension with an AHI greater than 15, and thus treatment is warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 and associated symptoms, the CMS document concluded that the data from three randomized controlled trials demonstrated improved daytime somnolence and functioning in those treated with CPAP.

In 2008, CMS expanded coverage of CPAP to include those beneficiaries with a diagnosis of OSA made with a combination of a clinical evaluation and unattended home sleep monitoring using a device with at least three channels. The coverage of CPAP would initially be limited to a 12-week period to identify beneficiaries diagnosed with OSA who benefit from CPAP. This is a change from prior coverage, which specified that PSG must be performed in a facility-based sleep study laboratory and not in a home or a mobile facility. The CMS defines AHI as the average number of episodes of apnea and hypopnea per hour of sleep, while the RDI is equal to the average number of respiratory disturbances per hour of continuous monitoring. There is variability in the published medical literature about the definition of the events that constitute a respiratory disturbance, and for the purposes of this national coverage decision, a respiratory disturbance is defined in the context of the sleep test technology of interest and, for portable monitoring devices that do not measure AHI or RDI directly, does not require direct measurement of airflow.

Effective for claims with dates of service on and after March 13, 2008, CMS determines that CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under the following situations:

1. The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. Continuous positive airway pressure is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.
2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.
3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
   a. attended PSG performed in a sleep laboratory; or
   b. unattended home sleep test with a type II home sleep monitoring device; or
   c. unattended home sleep test with a type III home sleep monitoring device; or
   d. unattended home sleep test with a type IV home sleep monitoring device that measures at least 3 channels.
4. The sleep test must have been previously ordered by the beneficiary’s treating physician and furnished under appropriate physician supervision.
5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criteria using the AHI or RDI are met:
   a. AHI or RDI greater than or equal to 15 events per hour, or
   b. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at minimum the number of events that would have been required in a 2-hour period.
7. Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.
8. Coverage with Evidence Development: Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1–7 cited here. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions
    a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and types II, III, and IV home sleep test in identifying subjects with OSA who will respond to CPAP?
    b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or types II, III, and IV home sleep test, does CPAP cause clinically meaningful harm?

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

The CMS finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA:

1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. A type II or type III sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
3. A type IV sleep testing device measuring three or more channels, one of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
4. A sleep testing device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.

Rationale/Source

As described in Cochrane reviews from 2006, treatment of OSA with CPAP or oral appliances has been shown to improve objective and subjective symptoms in patients with OSA. This policy focuses, therefore, on patient selection criteria for PSG, or sleep study, and the use of home sleep studies as an alternative to a supervised laboratory study. In addition, the use of EPAP, auto-adjusting CPAP (APAP) or BiPAP in patients with OSA is reviewed.

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328
Original Effective Date: 07/27/2012
Current Effective Date: 03/19/2014

Diagnosis and Treatment
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 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. 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, 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.

Portable Home Monitors
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).

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 OSA-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 OSA-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.
- Type 3 monitors may have the ability to predict AHI suggestive of OSA-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 OSA-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 OSA-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-OSA-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 OSA-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 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. 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.

Ambulatory Diagnosis and Management by a Sleep Specialist

In 2012 Rosen et al. published results from the HomePAP study, reporting that a home-based strategy for diagnosis and treatment of OSA was non-inferior to in-laboratory PSG. HomePAP was an independently-funded multi-center trial of 373 patients with a high pre-test probability of moderate to severe OSA. All of the study sites were accredited by a professional sleep medicine society and staffed by sleep medicine specialists. The clinical algorithm used to determine a high pretest probability of OSA was an ESS of 12 or greater and an “adjusted neck circumference” of at least 43 cm, calculated as the measured neck circumference plus an additional 3 cm if habitual snoring was present; 4 cm if hypertension was present; and 3 cm if apnea, gasping, or choking was present on most nights. Patients were randomized to diagnosis with limited channel portable sleep studies (airflow, respiratory effort, oxygen saturation, electrocardiogram, and body position) and titration with APAP, or to laboratory-based PSG with CPAP titration. Patients in the

home arm were asked to undergo in-lab PSG if the recording was technically unacceptable or if the AHI was less than 15. Repeat in-lab PSG was required in 11.1% of patients while the technical failure rate in the home arm was 21.4%. About half the patients in each study arm were diagnosed with an AHI of 15 or more and were eligible to continue to titration. At 3 months, patients in the home arm were using CPAP 1 hour more per night (4.7 vs. 3.7 hr) and had higher adherence (62.8% of nights had > 4 hr use vs. 49.4%). The 2 strategies were similar for acceptance of CPAP therapy, titration pressures, effective titrations, time to treatment, and improvement in ESS scores.

Several other randomized studies have found outcomes to be similar between home diagnosis and treatment in comparison with hospital-based diagnosis (PSG) and treatment (titration) when both strategies are supervised by a sleep medicine specialist. Kuna et al. conducted a noninferiority trial that compared home testing with a type 3 portable monitor followed by at least 3 nights of APAP versus in-laboratory titration and testing in 296 patients. Patients with an AHI of 15 or more on home monitoring were scheduled for 4- to 5-day APAP titration, while patients with an AHI of less than 15 per hour on home monitoring underwent in-laboratory PSG. Improvement in ESS, Center for Epidemiologic Studies Depression Scale (CES-D), metal component of the SF-12, and Functional Outcomes of Sleep Questionnaire (FOSQ) was similar for home-based and hospital-based treatment, meeting noninferiority parameters. In another study, 66 patients with a high level of clinical suspicion of OSA (ESS > 12 and a Sleep Apnea Clinical Score > 15) were randomized to home respiratory polygraphy and home follow-up, hospital PSG and hospital follow-up, or home respiratory polygraphy and hospital follow-up. Continuous positive airway pressure was calculated mathematically. At 6-month follow-up, significantly more patients in the home group were compliant (73%) compared to the hospital-based groups (68% and 57%). Other outcomes (e.g., ESS, functional outcomes of sleep) did not differ between the groups.

Skomro et al. conducted a randomized trial (102 patients) of home testing followed by one week of APAP, compared with in-laboratory PSG followed by CPAP titration. 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 two 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 four 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 four 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 (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).

Garcia-Diaz and colleagues assessed the sensitivity and specificity of home respiratory polygraphy and actigraphy to diagnose OSA in relation to laboratory PSG. 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. 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.

Section Summary
A number of studies, including randomized controlled trials, indicate that for patients with a high probability of moderate-to-severe sleep apnea and no contraindications, a home-based strategy with a multiple channel device that is overseen by a sleep specialist results in outcomes that are roughly equivalent to in-hospital diagnosis and management, and some studies report that compliance with treatment is better following a home-based strategy.

Use of APAP for Diagnosis and Treatment with Supervision by a Sleep Specialist
Mulgrew et al. published a randomized validation study of the diagnosis and management of OSA with a single channel monitor followed by APAP. They developed a diagnostic algorithm (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. 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).

Senn and colleagues assessed whether an empiric approach, using only a 2-week trial of APAP, could be effective for the diagnosis of OSA. Patients (n = 76) were included in the study if they had been referred by primary care physicians for evaluation of suspected OSA, were habitual snorers, complained of daytime sleepiness, and had an ESS score of 8 or greater (mean 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 two 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.

Monitoring of APAP use by daily transmission to a web-based database and review by a research coordinator was shown to improve compliance to PAP therapy (191 vs. 105 min/day). For the telemedicine arm of this randomized trial, the research coordinator reviewed the transmitted data daily and contacted the patient if any of the following were present: mask leak greater than 40 L/min for greater than 30% of the night, less than 4 hours of use for 2 consecutive nights, machine measured AHI more than 10 events/hr, and 90^{th} percentile of pressure greater than 16 cm H_2O. Evaluation by their physician sleep specialist after 3 months of therapy showed a similar decrease in AHI for the 2 groups (1.6 for telemedicine and 0.7 for controls).

Primary Care vs. Specialist Care

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

Peripheral Arterial Tone

In 2009, CMS issued a coverage decision to accept use of a sleep testing device that included actigraphy, oximetry and peripheral arterial tone to aid the diagnosis of OSA in beneficiaries who have signs and

symptoms indicative of OSA. A literature review of this technology in September 2009 identified a review of use of peripheral arterial tone for detecting sleep disordered breathing. This review includes the critical evaluation of a number of studies comparing the Watch-PAT™‡ with laboratory-based PSG. 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. 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 two 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 (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 two 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 six 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 three months. 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 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). (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. 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. 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 conventionally used for in-laboratory PSG. At this time, evidence is insufficient to support a change in the sensors required for portable monitoring.

Telemonitoring

No studies have been identified that compared unattended home sleep studies versus remotely monitored home sleep studies using type 3 devices. Two studies were identified that evaluated telemonitored PSG.

The most relevant study is a 2008 report by Kayyali et al. that used real-time monitoring of a 14-channel wireless device in the patient's own home. Patients came to the physician's office for application of the electrodes and sensors, then took a laptop computer home with them and called the sleep technologist when they were going to bed. Using a wearable radiofrequency transmitter, data were sent to the laptop computer in the patient's home which then transmitted the data to a monitoring center via cellphone. If any of the channels or video camera needed adjustments, the technologist would call the patient for intervention. In this validation study, 1 of 10 overnight PSG recordings required a phone call in the middle of the night to adjust an airflow sensor.

A study from 1999 compared consecutive nights of telemonitored PSG versus home PSG in 99 patients. The telemonitored PSG took place in community hospitals that did not have a dedicated sleep center, and the sleep technician who was monitoring the studies remotely could call the on-duty nurse to attempt to correct the technical problem. For the home PSG, electrodes were placed by an experienced technician and the patient went home for the night, returning to the sleep laboratory the next morning to return the equipment and the recording. The 2 nights of PSG were conducted in a randomized order. The primary endpoint was at least 3 hours of legible recordings. The failure rate for home studies was 23.4% and the failure rate of telemonitored hospital studies was 11.2%. Four of the failures of home PSG were due to an insufficient total sleep time and 10 were due to electrode detachments. It was noted that there is a risk of detachment of the PSG electrodes on the way home. This would not be as much of an issue with a type 3 device, particularly if the set-up was performed in the patient's home. Nine failures (9.1%) in this study were due to a problem with the thermistor.

Treatment

BiPAP and APAP

A 1995 study by Reeves-Hoche et al. randomized patients with OSA to receive either CPAP or BiPAP. 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.

Evidence-based guidelines from the AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals. As indicated in the 2011 AHRQ CER, increased compliance with APAP devices has not been well-documented in clinical trials. 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. 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.

PAP-NAP

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

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

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328
Original Effective Date: 07/27/2012
Current Effective Date: 03/19/2014

Oral Appliance Therapy

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

Nasal 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. 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.

An open-label extension of the 2011 randomized study by Berry et al. evaluated 12-month safety and durability of the treatment response in patients who had an initial favorable response to EPAP. Included were 41 patients (32% of 127) in the EPAP arm of the study who used the device for an average of at least 4 hours per night on at least 5 nights per week during months 1 and 2 and had at least a 50% reduction in AHI, or reduction to less than 10 events per hour, compared to the device-off PSG. Of the 51 patients (40% of 127) eligible, 41 enrolled in the extension study, and 34 (27% of 127) were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events per hour; the percentage of patients who met criteria for success was not reported. The arousal index was modestly decreased (from 23.9 to 19.0). Over 12 months of treatment, the ESS decreased from 11.1 to 6.0. The median percentage of reported nights used (entire night) was 89.3%. Device-related adverse events were reported by 42% of

patients, and the most frequently reported adverse events were difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study is limited by the inclusion of responders only and by the potential for a placebo effect on the ESS. However, the data suggest that some patients may respond to this device, and the patient compliance data might indicate a positive effect on daytime sleepiness that leads to continued use of the device in about 1 in 4 patients. Additional controlled studies are needed to distinguish between these alternatives.

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

Clinical Input Received 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.

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.

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.

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. No evidence was identified on the oral therapy device. Evidence at this time is insufficient to permit conclusions regarding the effect of these technologies on health outcomes. One comparative trial with historical controls was identified on use of a PAP-NAP study for patients with complex insomnia who are resistant to CPAP titration or use. Additional study is needed to evaluate the efficacy of this intervention with greater certainty.

Practice Guidelines and Position Statements
The patient selection criteria for a PSG or sleep study require an estimate of the pretest probability of OSA, based on the signs and symptoms of OSA. Ideally, one would like to know the necessity of a PSG (i.e., with 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. 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. 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 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. 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. 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.

Evidence-based guidelines on BiPAP, APAP, and dental appliances have been published by the AASM. The Practice Parameters provided a recommendation of “guideline” (moderate clinical certainty) that although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer oral appliances to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change. Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Oral appliances should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures. There was moderate clinical certainty that BiPAP was appropriate as an optional therapy in some cases in which high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation present. APAP was not recommended to diagnose OSA, for split-night studies or for patients with heart failure, significant lung disease such as chronic obstructive pulmonary disease, patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (e.g., obesity hypoventilation syndrome), patients who do not snore, and patients who have central sleep apnea syndromes. Unattended APAP in patients without significant comorbidities was considered an option (uncertain clinical use). The guidelines indicated that patients being treated on the basis of APAP titration must have close clinical follow-up to determine treatment effectiveness and safety, especially during the first few weeks of PAP use, and a 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 PSG in children in 2011. “Standard” recommendations were made for the following: PSG in children should be performed and interpreted in accordance with the AASM Manual for the Scoring of Sleep and Associated Events; PSG is indicated when the clinical assessment suggests the diagnosis of OSA in children; children with mild OSA preoperatively should have clinical evaluation following adenotonsillectomy to assess for residual symptoms. If there are residual symptoms of OSA, PSG should be performed; PSG is indicated following adenotonsillectomy to assess for residual OSA in children with preoperative evidence for moderate to

severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, and neurologic disorders; PSG is indicated for positive airway pressure titration in children with OSA.

The American Academy of Pediatrics (AAP) published a 2012 guideline on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting, which updates the AAP's 2002 guidelines. The AAP recommends that all children/adolescents should be screened for snoring, and PSG should be performed in children/adolescents with snoring and symptoms/signs of OSA as listed in the guideline. If PSG is not available, an alternative diagnostic test or referral to a specialist may be considered (Option). The estimated prevalence rates of OSA in children/adolescents range from 1.2% to 5.7%. Adenotonsillectomy is recommended as the first line of treatment for patients with adenotonsillar hypertrophy, and patients should be reassessed clinically post-operatively to determine whether additional treatment is required. High-risk patients should be re-evaluated with an objective test or referred to a sleep specialist. CPAP is recommended if adenotonsillectomy is not performed or if OSA persists postoperatively. Weight loss is recommended in addition to other therapy in patients who are overweight or obese, and intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

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

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

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328
Original Effective Date: 07/27/2012
Current Effective Date: 03/19/2014

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HCPCS Codes	E0485, E0486, G0398, G0399, G0400
ICD-9 Diagnosis	327.0 thru 327.9, 780.51, 781.53, 780.57
ICD-9 Procedure	89.17, 89.18, 93.90

Policy History

Original Effective Date: 07/27/2013
Current Effective Date: 03/19/2014
06/28/2012 Medical Policy Committee review

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Policy # 00328
Original Effective Date: 07/27/2012
Current Effective Date: 03/19/2014

07/27/2012	Medical Policy Implementation Committee approval. Split our current policy into three separate policies to track BCBSA. Auto-adjusting CPAP to initiate and titrate CPAP in adult patients with clinically significant OSA was changed from a 2 week trial to a 4 week trial.
01/23/2013	Coding updated
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. Clarification of a single night for a home sleep study. PAP-NAP studies considered investigational. Oral pressure therapy added as investigational.
03/19/2014	Medical Policy Implementation Committee approval. Not medically necessary statement reworded to state "Based on review of available data, the Company considers multiple sleep latency testing in the diagnosis of obstructive sleep apnea (OSA), except to exclude or confirm narcolepsy or other hypersomnia syndromes, in the diagnostic workup of obstructive sleep apnea (OSA) syndrome to be not medically necessary.**"

Next Scheduled Review Date: 03/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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    3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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