Supervised polysomnography (PSG) performed in a sleep laboratory **may be considered medically necessary** as a diagnostic test in patients with any of the following:

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

**UNSUPERVISED STUDIES**

Unattended (unsupervised) home sleep studies with a minimum of 4 recording channels (including oxygen saturation, respiratory movement, airflow, and
electrocardiogram (EKG) or heart rate) may be considered medically necessary in adult patients who meet criteria listed above for supervised PSG and have no evidence by history and physical examination of a health condition that might alter ventilation or require alternative treatment, including any of the following:

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

Unattended (unsupervised) sleep studies are considered experimental, investigational and/or unproven in adult patients who are considered at low to moderate risk for OSA.

Unattended (unsupervised) sleep studies are considered experimental, investigational and unproven, in pediatric patients (i.e., younger than 18 years of age).

REPEAT SUPERVISED STUDIES

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

- To initiate and titrate continuous positive airway pressure (CPAP) in adult patients with clinically significant OSA defined as those patients who have:
  1. Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour, or
  2. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, documented hypertension, ischemic heart disease, or history of stroke.

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

NOTE: This does not imply that supervised studies are needed routinely following unattended studies.

REPEAT UNSUPERVISED STUDIES

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

1. To assess efficacy of surgery or oral appliances/devices; OR
2. To re-evaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued.

MULTIPLE SLEEP LATENCY TESTING

Multiple Sleep Latency Test (MSLT) may be considered medically necessary to confirm the diagnosis of narcolepsy on the day following a PSG if the PSG is negative for OSA.

MAINTENANCE OF WAKEFULNESS TESTING

Maintenance of Wakefulness (MWT) testing is considered experimental, investigational and/or unproven.

NOTE: In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 is considered severe.

NOTE: A split-night study, in which severe OSA is documented during the first portion of the study using polysomnography, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP.

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

MEDICAL MANAGEMENT

CPAP/APAP/BiPAP

CPAP may be considered medically necessary in adult or pediatric patients with clinically significant OSA.

Auto-adjusting CPAP (APAP) may be considered medically necessary during a 2-week trial to initiate and titrate CPAP in adult patients with clinically significant OSA.

Bilevel positive airway pressure (BiPAP) without backup rate feature or APAP may be considered medically necessary in patients:

- With clinically significant OSA, AND
- Who have failed a prior trial of CPAP or for whom BiPAP is found to be more effective in the sleep lab.

Bilevel positive airway pressure (BiPAP) with back-up rate feature [e.g. VPAP Adapt™ from ResMed, and BiPAP AutoSV Advanced from Respironics, Inc] may be considered medically necessary in patients:

- With a diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA); AND
- Who have documented improvement of sleep-associated hypoventilation with the device on prescribed FIO2 and pressure settings.

NOTE: This medical policy only addresses BiPAP with back-up feature associated with sleep related breathing disorders. This device may be used for other diagnoses including, but not limited to, restrictive thoracic disorders,
severe COPD and hypoventilation syndromes. These conditions are not addressed in this medical policy.

**INTRAORAL APPLIANCES**

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) **may be considered medically necessary** in patients with mild to moderate OSA who prefer oral appliances (OA) to CPAP, or who do not respond to CPAP, or are not appropriate candidates for CPAP, that meet all of the following conditions:

1. The device is prescribed by a treating physician, and
2. The device is custom-fitted by qualified dental personnel, and
3. There is absence of temporomandibular dysfunction or periodontal disease, **AND**

Either:

- **MILD OSA**: Apnea/hypopnea index (AHI) or respiratory disturbance index (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, insomnia, documented hypertension, ischemic heart disease, or history of stroke,

OR

- **MODERATE OSA**: AHI or RDI greater than or equal to 15 events per hour, but less than or equal to 29 events per hour.

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

Oral pressure therapy (OPT) (e.g. Winx™, Apnicure, Inc.) to treat OSA is **considered experimental, investigational and/or unproven**.

A nasal expiratory positive airway pressure (EPAP) device (e.g., PROVENT) is **considered experimental, investigational and/or unproven**.

**ACTIGRAPHY**

Actigraphy is **considered experimental, investigational and/or unproven** for the routine diagnosis, assessments of severity, or management of any of the sleep disorders, including the insomnias, obstructive sleep apnea syndrome or periodic limb movement disorder.

**NOTE**: Surgical management of OSA is addressed on SUR706.009 Sleep Related Breathing Disorders: Surgical Management.

**Description:**

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

**DIAGNOSIS**

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. OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to daytime sleepiness.

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

1. Sitting and reading
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 (MSLT) measures how quickly the patient falls asleep when instructed to relax in a quiet and dimly lit room, and the maintenance of wakefulness test measures sleep latency when the patient is instructed to attempt to remain awake in an unstimulating environment. These tests are not considered necessary to evaluate sleep apnea, but the multiple sleep latency test may be used when symptoms, including excessive daytime sleepiness, suggest narcolepsy.

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

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

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

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

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

The first three elements listed here (EEG, submental electromyogram, and electro-oculogram) are required for sleep staging. By definition, a polysomnogram always includes sleep staging, while a cardiorespiratory "sleep study" does not. The actual components of the study will be dictated by the clinical situation. Supervision of the test may be considered important to ensure that the monitors are attached appropriately to the patient and do not become dislodged during the night. In addition, an attendant can identify severe OSA so that continuous airway pressure can be instituted in the second part of the night, and the most effective level of 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 respiratory event related arousals (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, 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, and an AHI of 15 or greater is considered severe. Although there is poor correlation between AHI and OSA symptoms, an increase in mortality is associated with an AHI of greater than 15 in adults. Mortality has not been shown to be increased in adult patients with an AHI between 5 (considered normal) and 15. Sources of measurement error with polysomnography include data loss, artifact, event recognition errors, measurement errors, use of different types of leads, and night-to-night variability.

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

In the current (2005) practice parameters of the American Academy of Sleep Medicine (1), there are four types of monitoring procedures:

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

Types 1 and 2 would be considered polysomnographic studies, and Types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and polysomnography are often used interchangeably.

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.

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.

(1, 2) 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 polysomnography [PSG] followed by CPAP titration during PSG on the same night) is an alternative to one full night of diagnostic PSG followed by a second night of titration if the following four criteria are met (1):

1. An apnea/hypopnea index (AHI) of at least 40 is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI of 20 to 40, based on clinical judgment (e.g., if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP pressure requirements, based on split-night studies, may be less accurate than in full-night calibrations.

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

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

4. 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.

The MSLT is an objective measure of the tendency to fall asleep in the absence of alerting factors, while the maintenance of wakefulness test (MWT) is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). (3) The MSLT and MWT are not routinely indicated in the evaluation and diagnosis of OSA or in assessment of change following treatment with CPAP. The MSLT may be indicated as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis (often characterized by cataplexy, sleep paralysis, and hypnagogic/hypnopompic hallucinations) or to differentiate between suspected idiopathic hypersomnia and narcolepsy. Narcolepsy and OSA can co-occur. (3, 4) Since it is not possible to differentiate the excessive sleepiness caused by OSA and narcolepsy, the OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.

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

**MEDICAL MANAGEMENT**

Medical management of OSA includes weight loss, oral appliances, and various types of positive pressure therapy (i.e., fixed CPAP, bilevel positive airway pressure [BiPAP], or auto-adjusting CPAP). CPAP involves the
administration of air, usually through the nose, by an external device at a fixed pressure to maintain the patency of the upper airway. Bilevel positive airway pressure is similar to CPAP, but these devices are capable of generating 2 adjustable pressure levels. Auto-adjusting CPAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been hypothesized that both bilevel positive airway pressure and auto-adjusting CPAP are more comfortable for the patient and thus might improve patient compliance or acceptance. Oral appliances can be broadly categorized as mandibular advancing/positioning devices or tongue-retaining devices. Oral appliances can either be “off the shelf” or custom made for the patient by a dental laboratory or similar provider. A number of oral appliances have received marketing clearance through the U.S. Food and Drug Administration’s (FDA) 510(k) pathway (product code LQZ) for the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™, LambergSleepWell-Smartrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, Desra, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device. 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.

The Winx Sleep Therapy System is an intraoral pressure gradient device that is intended for home use and proposed to treat OSA in adults. The mouthpiece is placed in the patient’s mouth and worn during sleep. A gentle, negative pressure is generated from the console to hold the tongue and soft palate out of the airway. Clinicians can download patient usage data from the console and review usage of the device (62).

ACTIGRAPHY

Actigraphy refers to the assessment of activity patterns by devices typically placed on the wrist or ankle that record body movement, which is interpreted by computer algorithms as periods of sleep and wake. Sleep/wake cycles may be altered in sleep disorders including insomnia, circadian rhythm sleep disorders, sleep-related breathing disorders, restless legs syndrome, and periodic limb movement disorder. In addition, actigraphy could potentially be used to assess sleep/wake disturbances associated with numerous other diseases or disorders such as attention-deficit/hyperactivity disorder, chronic fatigue syndrome, asthma, Parkinson’s syndrome, post-surgical delirium, stroke, advanced cancer, and intensive care monitoring.

Actigraphic devices are typically placed on the non-dominant wrist with a wristband and are worn continuously for at least 24 hours. Activity is usually recorded for a period of 3 days to 2 weeks but can be collected continuously over extended time periods with regular downloading of data onto a computer. The activity monitors may also be placed on the ankle for the assessment of restless legs syndrome, or on the trunk to record movement in infants. The algorithms for detection of movement are variable among devices and may include “time above threshold,” the “zero crossing method,” or “digital integration” method, resulting in different sensitivities. Sensitivity settings (e.g.,
low, medium, high, automatic) can also be adjusted during data analysis. The digital integration method reflects both acceleration and amplitude of movement; this form of data analysis may be most commonly used today. Data on patient bed times (lights out) and rise times (lights on) are usually entered into the computer record from daily patient sleep logs or by patient-activated event markers. Proprietary software is then used to calculate periods of sleep based on the absence of detectable movement, along with movement-related periods of wake. In addition to providing graphic depiction of the activity pattern, device-specific software may analyze and report a variety of sleep parameters including sleep onset, sleep offset, sleep latency, total sleep duration, and wake after sleep onset. Actigraphy has been used for more than 2 decades as an outcome measure in sleep disorders research. Numerous actigraphy devices have received FDA approval through the 510(k) process. Actigraphy devices designed and marketed to measure physical activity might also be used to measure sleep.

**Rationale:**

This policy was originally developed in 1990 and has been updated with periodic searches of scientific literature. This section of the current policy has been substantially revised. The following is a summary of the key literature to date.

As described in Cochrane reviews from 2006, treatment of obstructive sleep apnea (OSA) with continuous positive airway pressure (CPAP) or oral appliances has been shown to improve objective and subjective symptoms in patients with obstructive sleep apnea. (5, 6) This policy focuses, therefore, on patient selection criteria for polysomnography (PSG), or sleep study, and the use of home sleep studies as an alternative to a supervised laboratory study. In addition, the use of expiratory positive airway pressure (EPAP), auto-adjusting CPAP (APAP) or bilevel positive airway pressure (BiPAP) in patients with OSA is reviewed.

**DIAGNOSIS**

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

In 2011, the Agency for Healthcare Research and Quality (AHRQ) conducted a comparative effectiveness review (CER) on the diagnosis and treatment of OSA in adults. (7) The CER found strong evidence that an AHI greater than 30 events/hour is an independent predictor of all-cause mortality, with low or insufficient evidence for an association between AHI and other clinical outcomes. The CER found moderate evidence that type 3 and type 4
monitors may have the ability to accurately predict AHI suggestive of OSA and that type 3 monitors perform better than type 4 monitors at AHI cutoffs of 5, 10, and 15 events per hour. Despite no or weak evidence for an effect of CPAP on clinical outcomes, given the large magnitude of effect on the intermediate outcomes of AHI, Epworth Sleepiness Scale (ESS), and arousal index, the strength of evidence that CPAP is an effective treatment to alleviate sleep apnea signs and symptoms was rated moderate. The strength of the evidence that mandibular advancement devices improve sleep apnea signs and symptoms was rated moderate, and there was moderate evidence that CPAP is superior to mandibular advancement devices in improving sleep study measures.

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

Baseline AHI for other indices obtained from sleep studies is only modestly associated with response to CPAP or CPAP use among people with high (pre-test) probability for obstructive sleep apnea-hypopnea syndrome. None of the eligible studies assessed hard clinical outcomes (i.e., mortality, myocardial infarctions, strokes, and similar outcomes). Based on limited data, type 2 monitors may identify AHI suggestive of obstructive sleep apnea-hypopnea syndrome with high positive likelihood ratios (>10) and low negative likelihood ratios (<0.1) both when the portable monitors were studied in the sleep laboratory and at home. Type 3 monitors may have the ability to predict AHI suggestive of obstructive sleep apnea-hypopnea syndrome with high positive likelihood ratios and low negative likelihood ratios compared to laboratory-based PSG, especially when manual scoring is used. The ability of type 3 monitors to predict AHI suggestive of portable sleep apnea-hypopnea syndrome appears 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, at least for selected sensitivity and specificity pairs from receiver operating characteristic (ROC) curve analyses. Similarly to type 3 monitors, the ability of type 4 monitors to predict AHI suggestive of obstructive sleep apnea-hypopnea syndrome appears to be better in studies conducted in the specialized sleep unit compared to studies in the home setting. Studies of type 4 monitors that record one or two bioparameters also had high positive likelihood ratios and low negative likelihood ratios (>10) and low negative likelihood ratios (<0.1) both when the portable monitors were studied in the sleep laboratory and at home. The ability of type 4 monitors to predict AHI suggestive of obstructive sleep apnea-hypopnea syndrome appears in studies conducted in the specialized sleep unit compared to studies in the home setting. Patients older than the studied subjects (the median average age was approximately 50 years in the analyzed studies) may have more comorbidities that affect sleep (i.e., non-obstructive sleep apnea-hypopnea syndrome, chronic obstructive pulmonary disease, obesity hypoventilation syndrome, or periodic limb movements in sleep and restless leg syndrome). These conditions may be misdiagnosed if the sleep monitors do not record channels necessary for differential diagnosis from obstructive sleep apnea-hypopnea syndrome.
In 2008, the Centers for Medicare and Medicaid Services (CMS) implemented a national coverage decision allowing an initial 12-week period of CPAP based on a clinical evaluation and a positive sleep test performed with either an attended PSG performed in a sleep laboratory or an unattended home sleep test with a device that measures at least three channels. (9) Previously, coverage for CPAP required determination of AHI from attended PSG in a sleep laboratory, effectively establishing PSG-defined AHI as the only acceptable measure of OSA. As indicated in the AHRQ report, there is a poor correlation between AHI and daytime sleepiness, as well as between improvement in AHI and improvement of symptoms with CPAP usage. In addition, effectiveness of CPAP is affected by tolerance to the device (mask and airway pressure) and ultimately by compliance with treatment. These issues raise the question of whether PSG-defined AHI and manual titration of CPAP should remain the only means for diagnosis and treatment of OSA. Therefore, this policy evaluates the literature on the clinical utility of portable monitoring devices to identify patients with a high likelihood of benefit from treatment, without increasing potential harm from misdiagnosis.

Mulgrew et al. published a randomized validation study of the diagnosis and management of OSA with a single channel monitor followed by APAP. (10) They developed a diagnostic algorithm (Epworth Sleepiness Scale [ESS] score greater than 10, Sleep Apnea Clinical Score of 15 or greater, and a respiratory disturbance index [RDI] of 15 or greater on overnight oximetry) that was found to have a 94% positive predictive value for moderate to severe OSA assessed by PSG. Patients who passed the screening (n=68) were randomized to either attended in-laboratory PSG with CPAP titration or to home monitoring with a portable APAP unit. Home monitoring consisted of autotitration for 1 week, followed by download and assessment of efficacy data for the week (i.e., CPAP, mask leak, residual respiratory events, and use) and determination of the pressure for CPAP by the study physician. A second assessment of efficacy data was conducted for a week of CPAP use, and the pressure setting was adjusted by the CPAP coordinator in conjunction with the study physician. After 3 months of CPAP use, the subjects returned to the laboratory for PSG (with CPAP); no difference was observed between lab-PSG and home-managed patients in any of the outcome measures (median AHI of 3.2 vs. 2.5, median ESS of 5.0 vs. 5.0, and Sleep Apnea Quality-of-Life Index of 5.5 vs. 5.8, all respectively). Another study assessed the clinical utility of home oximetry in comparison with PSG by measuring the...
accuracy with which sleep physicians could predict which patients would benefit from treatment of OSA. (11) The primary outcome measure was the change in sleep apnea-specific quality of life after treatment. Subjects were randomly selected from a pool of referred patients; 307 were randomized, and 288 began a trial of CPAP. An additional 51 patients (18%) quit before the end of the 4-week CPAP trial; 31 indicated that they had trouble sleeping with CPAP, 3 removed the mask in their sleep, and 2 had nasal or sinus congestion. Overall, physicians predicted success in 50% of patients and 42% met the criterion for improvement. Outcomes of treatment were similar in the 2 groups, with improvements in ESS scores of 3.4 for home monitoring and 4.0 for PSG. The ability of physicians to predict the outcome of treatment was similar for the 2 methods. Five cases (2%) required PSG for diagnosis of other nonrespiratory sleep disorders (narcolepsy, periodic leg movements, and idiopathic hypersomnia).

Skomro et al. conducted a randomized trial (102 patients) of home testing followed by 1 week of APAP, compared with in-laboratory PSG followed by CPAP titration. (12) The study included adult patients with suspected OSA who had been referred to participating sleep medicine physicians at a tertiary sleep disorders clinic. Patients were included in the study if they had at least 2 symptoms of OSA (ESS >10, witnessed apneas, or snoring). The average ESS at baseline was 12.5. Exclusion criteria were respiratory or heart failure, clinical features of another sleep disorder, use of hypnotics, upper airway surgery, CPAP or oxygen therapy, pregnancy, or a safety-sensitive occupation. For home testing, a type 3 monitor was used that measured airflow, respiratory effort, oxygen saturation, heart rate, and body position, and home studies with technical failures or less than 4 hours of recording were repeated (17% of patients). After completion of testing and before application of APAP/CPAP, the subjects also underwent the other sleep test (home or laboratory). All studies were scored manually by a technician and reviewed by a sleep medicine physician, and subjects and investigators were blinded to the results of the second test. After sleep testing, 89 subjects received a diagnosis of OSA and were prescribed CPAP; 10 of those patients rejected CPAP treatment. In the home monitoring group, the proportion of subjects with an AHI greater than 30 was significantly lower, and the APAP-derived CPAP pressure was significantly higher than the manually-titrated CPAP pressure from the laboratory study. After 4 weeks of therapy, there were no significant differences between laboratory and home monitoring groups on any of the outcome measures; daytime sleepiness measured by the ESS (6.4 vs. 6.5), sleep quality measured by the Pittsburgh Sleep Quality Index (5.4 vs. 6.2), quality of life (4.5 vs. 4.6), Short-Form 36 (SF-36) Health Survey (62.2 vs. 64.1), blood pressure (129/84 vs. 125/81), or CPAP adherence (5.6 h/night vs. 5.4 h/night – all respectively).

Senn and colleagues assessed whether an empiric approach, using only a 2-week trial of APAP, could be effective for the diagnosis of OSA. (13) Patients (n=76) were included in the study if they had been referred by primary care physicians for evaluation of suspected OSA, were habitual snorers, complained of daytime sleepiness, and had an ESS score of 8 or greater (mean of 13.6). Exclusion criteria were contraindications to CPAP or APAP (heart failure, lung disease, obesity, hypoventilation syndrome), previous
diagnosis or treatments of a sleep disorder, or a diagnosis of an internal medical, neurologic, or psychiatric disorder explaining the symptoms. At the end of the 2-week trial, patients were asked to rate the perceived effect of treatment and to indicate whether they had used CPAP for more than 2 hours per night and were willing to continue treatment. Patients without a clear benefit of CPAP received further evaluation including clinical assessment and PSG. Compared with PSG, patient responses showed sensitivity of 80%, specificity of 97%, and positive and negative predictive values of 97% and 78%, respectively.

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

**Peripheral Arterial Tone**

In 2009, CMS issued a coverage decision to accept use of a sleep testing device that included actigraphy, oximetry, and peripheral arterial tone to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA. (16) A literature review of this technology in September 2009 identified a review of use of peripheral arterial tone for detecting sleep disordered breathing. (17) This review includes the critical evaluation of a number of studies comparing the Watch-PAT™ (a portable monitoring device for at-home use) with laboratory-based PSG. Relevant studies that included appropriate study populations (patients referred for evaluation of OSA or following CPAP treatment) are described.

Berry and colleagues randomized 106 patients who had been referred for a sleep study for suspected OSA at a local Veterans Administration center to portable monitoring followed by APAP (PM-APAP) or to PSG for diagnosis and treatment. (18) Patients were screened with a detailed sleep and medical history questionnaire including an ESS. To be included in the study, patients had to have an ESS score of 12 or greater and the presence of at least 2 of the following: loud habitual snoring, witnessed apnea/gasping, or treatment for hypertension. Patients on alpha-blockers or not in sinus rhythm were excluded due to the type of portable monitoring device used (Watch-PAT™ 100), which records sympathetic changes in peripheral arterial tone, heart rate, pulse oximetry, and actigraphy. Also excluded were patients with moderate to severe heart failure, use of nocturnal oxygen, chronic obstructive pulmonary disease, awake hypercapnia, neuromuscular disease, cataplexy, restless leg syndrome, use of narcotics, psychiatric disorder, shift work, or a prior
diagnostic study or treatment. Of the 53 patients randomized to PSG, 6 (11%) did not have PSG-defined OSA; 43 of 49 patients (88%) with CPAP titrations started on CPAP. In the portable monitoring arm, 4 of 53 patients (8%) were found not to have OSA. A physician affiliated with the sleep research laboratory reviewed the tracings for technical quality to determine if the events were correctly identified by the analysis program. Four studies (8%) were repeated due to technical failure or insufficient sleep. Patients with negative studies were then crossed over, which identified an additional 2 patients from the PSG arm as having OSA and 1 patient from the PM-APAP arm as having OSA. These patients (total of 50) had at least 1 APAP titration, 45 of the 50 (90%) had an adequate APAP titration and accepted treatment. Adherence was similar in the two groups, with 91% of patients in the PSG arm and 89% of patients in the PM-APAP arm continuing treatment at 6 weeks. Treatment outcomes were similar in the two groups, with a 7-point improvement in ESS score, 3-point improvement in the Functional Outcomes of Sleep Questionnaire, and a machine estimate of residual AHI of 3.5 in the PM-APAP group and 5.3 in the PSG group.

Pittman et al. evaluated residual OSA in 70 patients who had self-reported adherence to CPAP for at least 3 months. (19) Exclusion criteria for the study were diagnosis of periodic leg movement disorder, RDI less than 20 on diagnostic PSG, history of peripheral vascular disease, peripheral neuropathy, nonsinus cardiac rhythm, permanent pacemaker, severe lung disease, bilateral cervical or thoracic sympathectomy, finger deformity precluding sensor application, and use of alpha-adrenergic blockers. Compared to concurrently recorded PSG, the area under the curve (AUC) from receiver-operator characteristic (ROC) analysis for RDI greater than 15 was 0.95 (85% sensitivity and 90% specificity). Specificity decreased dramatically at lower cutoffs (67% for RDI >10 and 47% for an RDI >5). Another small study of 37 consecutive patients referred to a sleep center for OSA reported a high correlation between PSG and concurrently recorded Watch-PAT RDI (r=0.93). (20) (Correlation coefficients are not considered to be as meaningful as estimates of sensitivity and specificity.) Sensitivities for AHIs greater than 5, 15, and 35 in this study were 94%, 96%, and 83%, respectively. Specificity was reported at 80%, 79%, and 72%, respectively, for these thresholds.

Penzel and colleagues raised concern about the specificity of this device in an independently conducted small study of 21 patients with suspected sleep apnea. (21) The study found that for 16 of the 17 subjects with adequate recordings, the number of Watch-PAT events was greater than the number of respiratory events. The device was found to have reasonable reliability and to be very sensitive to arousal, although since arousals are not unique to apnea events, the authors concluded that the specificity of the Watch-PAT is limited. The long list of exclusion criteria in company-sponsored trials also raises questions about the clinical utility of the indirect measure of peripheral arterial tone in place of directly measuring airflow and respiratory effort. In a 2004 report, Pittman and colleagues noted other potential disadvantages of the Watch-PAT, including the inability to differentiate between the type of respiratory event (e.g., obstructive, central, mixed, or hypopnea) or to identify body position, and susceptibility to artifact from arrhythmias. (22) In this study, 28% of the cases did not achieve concordance (defined as both Watch-PAT and PSG RDI of >40 per hour, or within 10 events per hour in patients with an
RDI <40 per hour). It is noteworthy that the American Academy of Sleep Medicine (AASM) has not changed their 2007 guidelines, recommending that portable monitors should minimally record airflow, respiratory effort, and blood oxygenation, using biosensors conventionally used for in-laboratory PSG. (23) At this time, evidence is insufficient to support a change in the sensors required for portable monitoring.

Maintenance of Wakefulness (MWT) testing
The utility of Maintenance of Wakefulness Testing, in terms of improved health outcomes, has not been established. The 2005 AASM Practice Parameters note there are no standard or generally accepted guidelines for the performance of a MWT, and several variations in protocol exist, based on differences in definitions of sleep onset, trial duration and the need for previous night polysomnography. Normative data, sensitivity and specificity data in various patient groups are also lacking. Nevertheless, one suggested use has been testing an individual's ability to stay awake when public or personal safety issues are involved. However, the predictive value of MWT in this setting has not been established, and test results may not translate into behavior in workplace situations. Another potential use might be assessing the response to various treatments for disorders, such as sleep apnea or narcolepsy. However there are no established levels to indicate what represents a significant change in the test findings. Also, it is unclear that testing would provide useful information, over and above the patient's clinical response to therapy in these disorders, or would influence clinical decision-making, thereby improving patient health outcomes. The AASM concludes, “Future research is needed to define normative values using rigorous methods, to identify the impact of a standard clinical protocol for MWT, and to correlate the degree of sleepiness on objective testing with safety and occupational risks for the individual and for society in 'real life' circumstances.”

MEDICAL MANAGEMENT

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

Nasal Expiratory Positive Airway Pressure (EPAP)

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

In 2011, Berry et al. reported an industry-sponsored multicenter double-blind randomized sham-controlled trial of nasal EPAP. (32) Two-hundred and fifty patients with OSA and an AHI of 10 or more per hour were randomized to nasal EPAP (n=127) or a sham device (n=123) for 3 months. PSG was performed on 2 nights (device-on, device off, in a random order) at week 1 (92% follow-up) and after 3 months of treatment (78% follow-up). EPAP reduced the AHI from a median of 13.8 to 5.0 (-52.7%) at week 1 and from 14.4 to 5.6 (-42.7%) at 3 months. This was a significantly greater reduction in AHI than the sham group (-7.3% at week 1 and -10.1% at 3 months). Over 3 months, the decrease in ESS was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1 point difference in the ESS is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of 5 or more per hour on the device-off PSG night. The oxygenation results (oxygenation desaturation index and % of total sleep time with SpO2 <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduced to less than 10 (if device-off AHI was 10 or more), was greater in the EPAP group at 1 week (62% vs. 27.2%) and 3 months (50.7% vs. 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing the study due to adverse events. Overall, the validity of these results is limited by the high dropout rate, and the clinical significance of the results is uncertain.

An open-label extension of the 2011 randomized study by Berry et al. evaluated 12-month safety and durability of the treatment response in patients who had an initial favorable response to EPAP. (33) Included were 41 patients (32% of 127) in the EPAP arm of the study who used the device for an average of at least 4 hours per night on at least 5 nights per week during months 1 and 2 and had at least a 50% reduction in AHI, or reduction to less than 10 events per hour, compared to the device-off PSG. Of the 51 patients (40% of 127) eligible, 41 enrolled in the extension study, and 34 (27% of 127) were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events per hour; the percentage of patients who met criteria for success was not reported. The arousal index was modestly decreased (from 23.9 to 19.0). Over 12 months of treatment, the ESS decreased from 11.1 to 6.0. The median percentage of reported nights used
(entire night) was 89.3%. Device-related adverse events were reported by 42% of patients, and the most frequently reported adverse events were difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study is limited by the inclusion of responders only and by the potential for a placebo effect on the ESS. However, the data suggest that some patients may respond to this device, and the patient compliance data might indicate a positive effect on daytime sleepiness that leads to continued use of the device in about 1 in 4 patients. Additional controlled studies are needed to distinguish between these alternatives.

**Oral Pressure Therapy (OPT)**

Farid-Moayer, Siegel, et al. conducted a feasibility study of OPT for the treatment of OSA. In this single-center, proof-of-concept, single-treatment-night study, subjects with OSA underwent a baseline PSG study followed by PSG during use of an OPT system. The study included 54 men and 17 women, aged 53.2 ± 11.5 years (mean ± SD) had a baseline apnea-hypopnea index (AHI) greater than 5 events per hour. Results reported by the authors included that OPT was generally well tolerated with no serious adverse events. AHI decreased from 34.4 ± 28.9 events per hour (mean ± SD) at baseline to 20.7 ± 23.3 (p < 0.001). Treatment produced an AHI less than 10 in 48% of the subjects. The authors included that OPT significantly improved oxygen desaturation index (p < 0.001) and increased the percentage of the night with oxygen saturation of 90% or greater (p = 0.028). Stage-N1 sleep shifts, total sleep-stage shifts, awakenings and the percentage of sleep time spent in N1 sleep were significantly reduced with treatment. The authors concluded that OPT shows promise as a new treatment option for OSA in appropriate patients (63).

**Summary**

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

- Portable monitoring should only be conducted in adult patients with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation.
- A positive portable monitoring study with at least four channels of recording, including arterial oxygen saturation, airflow and respiratory effort, has a high positive predictive value for OSA and can be used as the basis for a CPAP trial to determine efficacy of treatment.
- A negative portable monitoring study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or have a positive study but do not respond to CPAP should undergo further evaluation.
- Due to the probability of artifacts or loss of data, raw data from the portable monitoring device should be interpreted by a sleep specialist. Follow-up and review of the APAP trial is also needed.

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

Use of the novel EPAP device has been reported in several prospective case
series and one industry-sponsored randomized controlled trial. The main
finding of this study was a decrease in AHI with minor impact on oxygenation
and the ESS. Evidence at this time is insufficient to permit conclusions
regarding the effect of this technology on health outcomes.

Due to the limited number of patients in the OPT feasibility study and no long
term results, the clinical significance of the results is uncertain, therefore OPT
is considered experimental, investigational and unproven.

Practice Guidelines and Position Statements

The patient selection criteria for a PSG or sleep study require an estimate of
the pretest probability of OSA, based on the signs and symptoms of OSA.
Ideally, one would like to know the necessity of a PSG (i.e., with
electroencephalography [EEG]) versus a sleep study (without EEG). A
detailed analysis of these issues is beyond the scope of this policy. However,
in 1997 the American Sleep Disorders Association (now the AASM) published
practice parameters for PSG and related procedures; these were most
recently updated in 2005. (1, 34) The guidelines suggested that patients had a
70% likelihood of having an AHI index of at least 10 if all of the following were
present: habitual snoring, excessive daytime sleepiness, a body mass index
greater than 35, and observed apneas. In 2005, full-night PSG was
recommended for the diagnosis of sleep-related breathing disorders and for
PAP titration in patients with an RDI of at least 15 per hour, or with an RDI of at
least 5 per hour in a patient with excessive daytime sleepiness. (1) For
patients in the high-pretest-probability stratification group, an attended
cardiorespiratory sleep study (type 3 with respiratory effort, airflow, arterial
oxygen saturation, and electrocardiogram [ECG] or heart rate) was considered
an acceptable alternative to full-night PSG, provided that repeat testing with
full-night PSG was permitted for symptomatic patients who had a negative
cardiorespiratory sleep study finding. In their 2005 Guidelines, AASM stated
that data were insufficient to support unattended portable sleep studies, but
they might be considered acceptable when the patient has severe symptoms
requiring immediate treatment and PSG is not available, the patient cannot be
studied in a sleep laboratory (i.e., nonambulatory), or for follow-up studies to
evaluate response to therapy. (1) The document further stated that, in these
patients, a sleep study may be an acceptable alternative to PSG. However, a
sleep study may only “rule in” disease, and PSG should be available for
patients with false-negative sleep study results. An additional recommendation
of note is that sleep studies were not recommended in patients with comorbid
conditions or secondary sleep complaints. Most of the literature reviewed
specifically excluded patients with comorbid conditions. A cardiorespiratory
sleep study without EEG recording was not recommended for CPAP titration, as sleep staging was considered necessary. Finally, practice parameters stated that a multiple sleep latency test is not routinely indicated for most patients with sleep-related breathing disorders.

Portable monitoring (PM) devices were addressed by a joint project of the AASM, the American Thoracic Society, and the American College of Chest Physicians in 2003. (35, 36) In 2007 the AASM issued revised guidelines for the use of unattended portable monitors, recommending that portable monitors should minimally record airflow, respiratory effort, and blood oxygenation, with biosensors conventionally used for in-laboratory PSG, and that testing be performed by an experienced sleep technologist and scored by a board-certified sleep medicine specialist under the auspices of an AASM-accredited comprehensive sleep medicine program. (23)

Evidence-based guidelines on BiPAP, APAP, and dental appliances have been published by the AASM. (25-28) The Practice Parameters provided a recommendation of “guideline” (moderate clinical certainty) that although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer oral appliances to CPAP, or who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change. Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Oral appliances should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures. There was moderate clinical certainty that BiPAP was appropriate as an optional therapy in some cases in which high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation present. (37) APAP was not recommended to diagnose OSA, for split-night studies or for patients with heart failure, significant lung disease such as chronic obstructive pulmonary disease, patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (e.g., obesity hypoventilation syndrome), patients who do not snore, and patients who have central sleep apnea syndromes. (28) Unattended APAP in patients without significant comorbidities was considered an option (uncertain clinical use). The guidelines indicated that patients being treated on the basis of APAP titration must have close clinical follow-up to determine treatment effectiveness and safety, especially during the first few weeks of PAP use, and a re-evaluation and, if necessary, a standard CPAP titration should be performed if symptoms do not resolve or if the APAP treatment otherwise appears to lack efficacy.

The AASM published evidence-based guidelines for respiratory indications for polysomnography in children in 2011. (38) “Standard” recommendations were made for the following: PSG in children should be performed and interpreted in accordance with the AASM Manual for the Scoring of Sleep and Associated Events; PSG is indicated when the clinical assessment suggests the diagnosis of OSA in children; children with mild OSA preoperatively should have clinical evaluation following adenotonsillectomy to assess for residual
symptoms. If there are residual symptoms of OSA, PSG should be performed; PSG is indicated following adenotonsillectomy to assess for residual OSA in children with preoperative evidence for moderate to severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, and neurologic disorders; PSG is indicated for positive airway pressure titration in children with OSA.

The American Academy of Otolaryngology – Head and Neck Surgery published clinical practice guidelines on PSG for sleep-disordered breathing prior to tonsillectomy in children in 2011. (39) The committee made the following recommendations: before determining the need for tonsillectomy, the clinician should refer children with sleep-disordered breathing for PSG if they exhibit certain complex medical conditions such as obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses; the clinician should advocate for PSG prior to tonsillectomy for sleep-disordered breathing in children without any of the comorbidities listed above for whom the need for surgery is uncertain or when there is discordance between tonsillar size of physical examination and the reported severity of sleep-disordered breathing; clinicians should communicate PSG results to the anesthesiologist prior to the induction of anesthesia for tonsillectomy; clinicians should admit children with OSA documented on PSG for inpatient, overnight monitoring after tonsillectomy if they are younger than age 3 years or have severe OSA (AHI of 10 or more, oxygen saturation nadir less than 80%, or both); in children for whom PSG is indicated to assess sleep-disordered breathing prior to tonsillectomy, clinicians should obtain laboratory-based PSG, when available.

The American Academy of Pediatrics (AAP) published a 2002 guideline on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting; complex high-risk patients should be referred to a specialist. (40) The AAP guidelines stated that diagnostic evaluation is useful in discriminating between primary snoring and OSA; although the gold standard is overnight PSG, other diagnostic tests such as PSG of daytime naps or home oximetry may be useful if results are positive. Adenotonsillectomy is the first line of treatment for most children, and CPAP is an option for those who are not candidates for surgery or do not respond to surgery; patients should be reevaluated post-operatively to determine whether additional treatment is required. No updates of this guideline have been identified.

In 2008 the United Kingdom’s National Institute for Health and Clinical Excellence (NICE) issued guidance on CPAP treatment of OSA, based on a review of the literature and expert opinion. (41) The recommendations included:

- Moderate to severe OSA/hypopnea syndrome (OSAHS) can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person’s home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually
assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the AHI or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5–14 in a sleep study, moderate when the AHI is 15–30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

- CPAP is recommended as a treatment option for adults with moderate or severe symptomatic OSAHS. CPAP is only recommended as a treatment option for adults with mild OSAHS if: they have symptoms that affect their quality of life and ability to go about their daily activities, and lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate.

- Treatments aim to reduce daytime sleepiness by reducing the number of episodes of apnea/hypopnea experienced during sleep. The alternatives to CPAP are lifestyle management, dental devices, and surgery. Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption. Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS. Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice.

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

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

ACTIGRAPHY

This section of the medical policy was initially based primarily on 2003 practice parameters issued by the AASM. (44) Since all the specific clinical indications for actigraphy were classified as guidelines or options, the AASM practice parameters indicated that all indications for actigraphy would be considered investigational. In a review paper that served as the basis for the 2003 practice parameters, (45) AASM pointed out the challenges in evaluating the diagnostic performance of actigraphy:

- Different actigraphy devices use different algorithms for the evaluation of data. There were no published articles comparing the different algorithms, making comparison between studies difficult.

- Polysomnography (PSG) is considered the gold standard for the evaluation of sleep/wake cycles. However, correlation data may be misleading. For example, a high correlation on total sleep time would mean that individuals who slept longer by PSG criteria also slept longer by actigraphy criteria; however, this would not exclude the possibility that actigraphy data overestimated total sleep time. Different methods of
analysis have also been used, such as accuracy for identification of true sleep and true wake epochs. The diagnostic performance will also vary according to how much time the patient is asleep. For example, malfunctioning records will falsely identify the patient as asleep. Finally, comparisons between PSG and actigraphy have to be time-locked; if the 2 technologies gradually drift apart, different time epochs may be compared with each other.

- Published reports of actigraphy must contain complete reporting of sensitivity, specificity, scoring algorithm, and filters, as well as reliability, validity, ruggedness, and artifact rejection for the device and computer program used.

The 2005 Update for the AASM Practice Parameters (46) continued to list actigraphy as an option and suggested areas such as restless legs syndrome and characterizing circadian rhythm patterns for further evaluation. No controlled studies had been conducted to compare the results of actigraphy to other methods to determine if actigraphy would provide incremental information that would result in improved health outcomes.

In 2007 the AASM published updated practice parameters on the use of actigraphy in the assessment of sleep and sleep disorders. (47) Whereas the 2005 practice parameters focused on the comparison of actigraphy with polysomnographically recorded sleep, the 2007 update included 108 additional studies comparing actigraphy to a number of standard clinical assessment tools that included sleep logs, subjective questionnaires, caregiver reports, and circadian phase markers. Actigraphy was recommended as a “standard” only as a method to estimate total sleep time in patients with obstructive sleep apnea syndrome when PSG is not available. Other indications changed from “option” to “ guideline” but failed to reach a recommendation of “standard” due primarily to the absence of high-quality trials. Few of the studies reviewed had provided technical details related to the administration and scoring of actigraphy. In addition, most of the studies lacked a description of blinding, and there was “an inadequate description of whether visual inspection of data is performed, how missing data is handled, and other important decisions made in the analysis of actigraphy data.” The AASM Standards of Practice Committee indicated the need for additional research in the following areas:

- Comparison of results from different actigraphy devices and the variety of algorithms used
- Standards for setting start and stop times
- Reliability and validity compared to reference standards
- Clarification of the relative and unique contributions of actigraphy, polysomnography, and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects

In AASM’s 2007 Practice Parameter on evaluation and treatment of circadian rhythm sleep disorders (CRSDs), the use of actigraphy was considered as either an option or guideline, depending on the suspected disorder. (48) Specifically, use of actigraphy was recommended as an option for diagnosis of irregular sleep-wake disorder and free-running disorder and as a guideline for diagnosis of advanced sleep phase disorder, delayed sleep phase
disorder, and shift work disorder. The evidence reviewed indicated good agreement between actigraphy and results of other diagnostic tools including polysomnography, sleep logs, and markers of circadian phase. It should be noted, however, that there is a relative lack of evidence for any procedure in the diagnosis or evaluation of treatment of CRSDs. For example, use of sleep logs received a guideline recommendation, based primarily on consensus and inclusion in the second edition of the International Classification of Sleep Disorders (ICSD-2). Insufficient evidence was found to recommend use of circadian phase markers for any CRSDs other than free-running disorder. Polysomnography is not routinely indicated for the diagnosis of CRSDs. (48)

Literature Review

Actigraphy is frequently used as an intermediate outcome in research studies. However, literature review updates have not identified any studies that evaluated whether the use of actigraphy would result in improved health outcomes for patients with sleep disorders (clinical utility). A number of studies have assessed sensitivity and specificity in either healthy or clinical populations (clinical validity). Following is a description of key studies to date.

Adults

Paquet et al. compared actigraphic assessment of sleep and wake with PSG under varying conditions of sleep disturbance (night time sleep, daytime sleep, daytime sleep with caffeine) in 23 healthy subjects. (49) Data were analyzed from a study that evaluated the effects of caffeine on daytime recovery sleep. The experimental protocol involved 2 visits to the sleep laboratory, each including one night of nocturnal sleep, one night of sleep deprivation, and the next day of recovery sleep (once with placebo and once with 200 mg caffeine). The Actiwatch® and PSG equipment were synchronized prior to recording, and assessment of sleep and wake were compared for each 1-minute interval to evaluate sensitivity, specificity, and accuracy of actigraphy in comparison with manually staged sleep from PSG recordings. Sensitivity was defined as the proportion of all epochs scored as sleep by PSG that were also scored as sleep by actigraphy. Specificity was the proportion of all epochs scored as wake by PSG that were also scored as wake by actigraphy. Accuracy was the proportion of all epochs correctly identified by actigraphy. Four different sensitivity settings/scoring algorithms were compared. In general, as the threshold to detect movement was raised, sensitivity to detect sleep increased, but the ability to detect wake (specificity) decreased. With the medium threshold algorithm, the sensitivity to detect sleep was 95–96%. However specificity, or the ability to detect wake, was 54% for night time sleep, 45% for daytime recovery sleep, and 37% for daytime recovery sleep with caffeine. A main finding of the study was that the more disturbed the sleep, the less the actigraph was able to differentiate between true sleep and quiet wakefulness, with an accuracy of 72% for the most disrupted sleep condition. Through experimental manipulation of the level of sleep disturbance, this study provides substantial information about the limitations of this technology for clinical populations with sleep disruption.

Several studies assessed clinical validity in patients with primary or secondary sleep disorders. A 2006 study assessed the sensitivity and specificity of actigraphy in comparison with PSG in older adults treated for chronic primary
insomnia. (50) Visual scoring of the PSG data was blinded, and actigraphic records were scored by proprietary software. The study found that actigraphy agreed with PSG scoring of sleep for 95% of the 30-second epochs (sensitivity), but agreed with PSG scoring of wake only 36% of the time (specificity). The authors concluded that, “the clinical utility of actigraphy is still suboptimal in older adults treated for chronic primary insomnia.”

Beecroft et al. reported an observational study of sleep monitoring in the intensive care unit, comparing nurse assessment, actigraphy, and PSG in 12 stable, critically ill, mechanically ventilated patients. (51) PSG showed severely disrupted sleep, with decreased total sleep time and sleep efficiency, high frequency of arousals and awakenings (fragmentation), and abnormal sleep architecture (decreased slow wave and rapid eye movement [REM] sleep). Both the nurse’s and the actigraphic assessment of sleep were found to be inaccurate. Actigraphy overestimated the total sleep time, with a median that was 2–3 hours greater than PSG. Median sleep efficiency (actual sleep as a percentage of total recording time) was estimated at 61–95% by actigraphy, depending on the sensitivity setting, which was substantially higher than the 42% median sleep efficiency shown by PSG with sleep staging. Actigraphy with a SOMNOwatch™ in patients (n=28) with sleep-disordered breathing showed a sensitivity of 90%, a specificity of 95%, and overall accuracy of 86% in comparison with PSG. (52) Correlations were high for total sleep time (0.89), sleep period time (0.91), and sleep latency (0.89), and moderate for sleep efficiency (0.71) and sustained sleep efficiency (0.65).

Studies continue to assess different modes of data collection and analysis, including varying the sensitivity settings for existing algorithms and developing new scoring algorithms. A 2011 publication compared 3 collection modes (proportional integration, time above threshold, and zero crossings) with PSG in 889 older community-dwelling men who participated in the Outcomes of Sleep Disorders in Men (MrOS) study. (53) The proportional integration mode was found to correspond best to PSG, with moderate interclass correlation coefficients of 0.32 to 0.57. Actigraphy in this mode overestimated total sleep time by an average of 13.2 minutes, with an absolute difference (positive or negative direction) of 52.9 minutes. There was a systematic bias for overestimating total sleep time which increased with decreasing sleep duration.

Children

Werner and colleagues assessed agreement between actigraphy and parent diary or questionnaire for sleep patterns in 50 children, aged 4–7 years, recruited from kindergarten schools in Switzerland. Sixty-eight families agreed to participate of 660 families invited (10%). (54) Each child was home-monitored with an actigraph for 6 to 8 consecutive nights, and parents were requested to complete a detailed sleep diary (15-minute intervals) during the monitoring days to indicate bedtime, estimated sleep start, wake periods during the night, and estimated sleep end. Parents’ assessment of habitual wake time, get up time, bedtime, time of lights off, sleep latency, and nap duration were obtained through questionnaire. Satisfactory agreement, defined a priori as differences smaller than 30 minutes, was achieved between actigraphy and diary for sleep start, sleep end, and assumed sleep.
Actual sleep time and nocturnal wake time differed by an average of 72 minutes and 55 minutes, respectively. Satisfactory agreement was not reached between actigraphy and questionnaire for any of the parameters. The authors concluded that the diary is a cost-effective and valid source of information about children's sleep-schedule time, while actigraphy may provide additional information about nocturnal wake time or may be used if parents are unable to report in detail. Compliance and accuracy in the diaries is likely to be affected by the motivation of the parents, who in this study were self-selected.

In 2011, O'Driscoll et al. reported a comparison of actigraphy with PSG in 130 children who had been referred for assessment of sleep-disordered breathing. (55) The arousal index and apnea-hypopnea index (AHI) scored from PSG were compared to the number of wake bouts/hour and actigraphic fragmentation index. Using a PSG-determined AHI of greater than 1 event/hour, the actigraphic measure of wake bouts/hour had a sensitivity and specificity of 14.9% and 98.8%, respectively, and the fragmentation index had a sensitivity and specificity of 12.8% and 97.6%, respectively. Using a PSG-determined arousal index greater than 10 events per hour as the reference standard, the actigraphic measure of wake bouts/hour had a sensitivity and specificity of 78.1% and 52.6% and the fragmentation index had a sensitivity and specificity of 82.2% and 50.9% - both respectively. Based on receiver operator characteristic (ROC) curves, the ability of actigraphic measures to correctly classify a child as having an AHI of greater than 1 event/hour was considered to be poor.

Another study examined the validity of actigraphy for determining sleep and wake in children with sleep disordered breathing with data analyzed over 4 separate activity threshold settings (low, medium, high, auto). (56) The low and auto activity thresholds were found to adequately determine sleep (relative to PSG) but significantly underestimated wake, with sensitivity of 97% and specificity of 39%. The medium- and high-activity thresholds significantly underestimated sleep time (sensitivity of 94% and 90%, respectively) but were not found to be significantly different from the total PSG estimates of wake time (specificity of 59% and 69%). Overall agreement rates between actigraphy and PSG (for both sleep and wake) were 85% to 89%.

A validation study of actigraphy for determining sleep and wake was conducted in 10 preterm infants using videotaped behavioral observations. (57) The study was conducted for a 24-hour period each week while the infants were in the nursery, resulting in a total of 38 studies. Wakefulness was scored as quiet wake with eyes open and "bright", active wake with eyes open and gross body movements, or crying. Sleep included quiet sleep with regular breathing and eyes closed, active sleep with irregular breathing and rapid eye movements, and indeterminate sleep, during which characteristics of both active and quiet sleep were observed. Behavioral sleep-wake scoring was carried out blinded to the knowledge of the actigraphy data. The actigraph, which was synchronized to the video recording, was placed in a custom-designed sleeve bandage and positioned on the infant's leg midway between the knee and ankle. The agreement rate between actigraphic determination of sleep and wake, and behavioral scoring ranged from 66% for the high sensitivity setting at the youngest gestational age (30–33 weeks) to 89% at
the low sensitivity setting for infants of 37–40 weeks’ gestational age. For the youngest infants, sensitivity and specificity at the low threshold were 88% and 34%, respectively. For infants of 37–40 weeks of gestational age, the sensitivity and specificity were 97% and 32%, respectively. Similar results (97% sensitivity and 24% specificity) were obtained with an epoch-by-epoch comparison of actigraphy and videosomnography in 22 autistic, 11 developmentally delayed, and 25 normally developing preschool children. (58)

Insana et al. compared ankle actigraphic recording and PSG in 22 healthy infants (13 to 15 months of age). (59) Actigraphy was found to underestimate total sleep time by 72 minutes and overestimate wake after sleep onset by 14 minutes. In 55% of the infants, total sleep time was underestimated by equal to or greater than 60 minutes. Sensitivity was calculated for total sleep time (92%), stages 1 and 2 combined (91%), slow wave sleep (96%), and REM sleep (89%). Specificity for identifying wake was 59%, and accuracy was 90%. Overall, actigraphy identified sleep relatively well but was unable to discriminate wake from sleep. Another study compared wrist actigraphy with PSG in 149 healthy school-aged children. (60) Although the sleep period time was not significantly different, actigraphy was found to underestimate total sleep time by 32 minutes (correlation coefficient of 0.47) and overestimate wake after sleep onset by 26 minutes (correlation coefficient of 0.09). The authors concluded that actigraphy is relatively inaccurate for the determination of sleep quality in this population.

Summary

The clinical validity of actigraphy depends, to a large extent, on the modality with which it is being compared.

- Comparisons with sleep diaries show reasonable correlations for measures of bedtime, sleep onset, and wake time. The relative and unique contributions of actigraphy and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects remains to be demonstrated.
- Comparisons with the more resource-intensive polysomnography or behavioral scoring indicate that, with the appropriate sensitivity threshold, actigraphy has sufficient sensitivity to detect sleep but has poor specificity in distinguishing between wake and sleep. The literature also indicates that the accuracy of actigraphy to differentiate between wake and sleep decreases as the level of sleep disturbance increases.

Overall, progress has been made since the 2007 AASM research recommendations in assessing the reliability and validity of different algorithms in comparison with the reference standard. Although actigraphy appears to provide reliable measures of sleep onset and wake time in some patient populations, the clinical utility of actigraphy over the less expensive sleep diary has not been demonstrated. Moreover, evidence indicates that actigraphy does not provide a reliable measure of sleep efficiency in clinical populations. Evidence to date does not indicate that this technology is as beneficial as the established alternatives. Therefore, actigraphy is considered experimental, investigational and unproven.

Practice Guidelines and Position Statements
The recommendations of the AASM are categorized as standards, guidelines, or options. Standards describe a generally accepted patient care strategy, which reflects a high degree of clinical certainty. Guidelines reflect a moderate degree of clinical certainty, while options imply either inconclusive or conflicting evidence or conflicting expert opinion. As noted here, there is only one recommendation considered a standard, and this addresses the technical performance of actigraphic devices (first bullet below). There is also only 1 recommended guideline (second bullet below), and this addresses the small subset of patients with insomnia and restless legs syndrome with specific indications. All of the other recommendations are considered options.

Recommendations of the AASM from 2003 (44):

- Actigraphy is reliable and valid for detecting sleep in normal, healthy adult populations. (Standard)
- Actigraphy is not indicated for the routine diagnosis, assessment of severity, or management of any of the sleep disorders. However, it may be useful in the assessment of specific aspects of insomnia (assessment of sleep variability, measurement of treatment effects, detection of sleep phase alterations), and restless legs syndrome/periodic limb movement (assessment of treatment effects). (Guideline)
- Actigraphy may be a useful adjunct to a detailed history, examination, and subjective sleep diary for the diagnosis and treatment of insomnia, circadian-rhythm disorders, and excessive sleepiness under certain conditions. (Option)
- The use of actigraphy may be useful in assessing daytime sleepiness in situations where a more standard technique, such as a multiple sleep latency test, is not practical. (Option)
- Actigraphy is an effective means of demonstrating multiday human rest-activity pattern in clinical situations in which a sleep log, observations, or other methods cannot provide similar information. (Option)
- Actigraphy may be useful in characterizing and monitoring circadian rhythm patterns or disturbances in elderly and nursing home patients, newborns, infants, children, and adolescents; hypertensive individuals; depressed or schizophrenic patients; and individuals in inaccessible situations (i.e., space flight). (Option)
- Actigraphy appears useful as an outcome measure in interventional trials in patients with sleep disorders, outcome studies of healthy adults, patients with certain medical and psychiatric conditions, and children and the elderly. (Option)
- Actigraphy may be useful in determining the rest-activity pattern during portable sleep apnea testing. However, the use of actigraphy alone in the detection of obstructive sleep apnea is not currently established. (Option)
- Actigraphic studies should be conducted for a minimum of 3 consecutive 24-hour periods, but this length of time is highly dependent on the specific use in a given individual. (Option)

A 2005 Update for the AASM practice parameters (46) continued to list actigraphy as an option and also suggested areas, such as restless legs syndrome and characterizing circadian rhythm patterns, for further evaluation.
Updated practice parameters in 2007 on the use of actigraphy in the assessment of sleep and sleep disorders (including a separate practice parameter on circadian rhythm sleep disorders) recommended actigraphy as a “standard” only as a method to estimate total sleep time in patients with obstructive sleep apnea syndrome when PSG is not available. (47,48) Other indications changed from option to guideline but failed to reach a recommendation of standard due primarily to the absence of high-quality trials.

Coding:

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

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.

CPT E0470 is used to describe BiPAP without back-up feature.

CPT E0471 is used to describe BiPAP with back-up feature

CODING:

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. Only the written coverage position in a medical policy should be used for such determinations.

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member’s benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

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## HCPCS Codes


## ICD-9 Diagnosis Codes

| 327.23, 780.09, 780.51, 780.53, 780.57 |

## ICD-9 Procedure Codes

| 89.17, 89.18, 93.90 |

## ICD-10 Diagnosis Codes

| F51.01-F51.9, G25.81, G47.00-G47.9, R06.81, R40.0 |

## ICD-10 Procedure Codes

| 4A1ZXQZ, 5A09357, 5A09358, 5A09457, 5A09458, 5A0945Z, 5A09557, 5A09558, 5A0955Z |

### Medicare Coverage:

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare’s National Coverage at [http://www.cms.hhs.gov](http://www.cms.hhs.gov).

### References:

**Obstructive Sleep Apnea references 1-43**  (Actigraphy references 45-61)

4. Ahmed I, Thorpy M. Clinical features, diagnosis and treatment of [Obstructive Sleep Apnea](http://www.medicalpolicy.hcsc.net/medicalpolicy/activePolicyPage?lid=...


20. Pang KP, Gourin CG, Terris DJ. A comparison of polysomnography and


Policy History:

3/15/2014 The following coverage changes were made for Intraoral appliances: 1) Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in patients with clinically significant OSA that meet all of the following conditions was replaced with: Intraoral appliances (tongue-retaining devices or
mandibular advancing/positioning devices) may be considered medically necessary in patients with mild to moderate OSA who prefer oral appliances (OA) to CPAP, or who do not respond to CPAP, or are not appropriate candidates for CPAP, that meet all of the following conditions. 2) Mild and Moderate OSA were defined, and 3) CPAP has failed or is contraindicated was removed was removed from “AHI or RDI greater than or equal to 15 events per hour, but less than or equal to 29 events per hour” statement.

10/1/2013 Document updated with literature review. Title changed from Sleep Related Breathing Disorders, Assessment and Diagnosis. Revised policy addresses Assessment, Diagnosis and Medical Management. Previously Medical Management was located on SUR706.009 Sleep Related Breathing Disorders, Medical and Surgical Management. Coverage has been changed- Under “Diagnosis”: 1) Supervised polysomnography performed in a sleep laboratory, unattended (unsupervised) home sleep studies with a minimum of 4 recording channels, repeated supervised polysomnography performed in a sleep laboratory and repeated unattended (unsupervised) home sleep studies with a minimum of four recording channel may be considered medically necessary when specific criteria are met. 2) Unattended (unsupervised) sleep studies are considered experimental, investigational and unproven in adult patients who are considered at low to moderate risk for OSA. Unattended (unsupervised) sleep studies are considered experimental, investigational and unproven, in pediatric patients (i.e., younger than 18 years of age). 3) Multiple Sleep Latency Test (MSLT) may be considered medically necessary to confirm the diagnosis of narcolepsy on the day following a PSG if the PSG is negative for OSA.; Under “Medical Management”: 1) CPAP, Auto-adjusting CPAP, Bilevel positive airway pressure (with or without back-up rate feature) and Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary when specific criteria are met. 2) A nasal expiratory positive airway pressure (EPAP) device (e.g., PROVENT) is considered experimental, investigational and unproven. 3) Oral Pressure Therapy (OPT) (e.g. Winx™, Apnicure, Inc.) to treat OSA is considered experimental, investigational and unproven.

8/15/2009 Policy updated with literature search. Coverage position changed to add conditional coverage of home sleep studies.

2/15/2009 Coverage revised

1/1/2009 New CPT/HCPCS code(s) added

11/15/2007 Revised/updated entire document

3/13/2006 Revised/updated entire document

11/1/2005 Revised/updated entire document

3/15/2005 Revised/updated entire document

1/2000 Revised/updated entire document

4/1999 Revised/updated entire document

9/1998 Revised/updated entire document

6/1998 Revised/updated entire document
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