

ATTENDED POLYSOMNOGRAPHY FOR EVALUATION OF SLEEP DISORDERS

Policy Number: 2014T0334Q
Effective Date: August 1, 2014

Table of Contents	Page	Related Policies:
BENEFIT CONSIDERATIONS	1	Obstructive Sleep Apnea Treatment
COVERAGE RATIONALE	2	
DEFINITIONS	4	
APPLICABLE CODES	7	
DESCRIPTION OF SERVICES	8	
CLINICAL EVIDENCE	11	
U.S. FOOD AND DRUG ADMINISTRATION CENTER FOR MEDICARE AND MEDICAID	17	
SERVICES	18	
REFERENCES	18	
POLICY HISTORY/REVISION INFORMATION	22	

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Plan Document Language

Before using this guideline, please check enrollee's specific plan document and any federal or state mandates, if applicable.

Indications for Coverage

1. Medical or surgical treatment of snoring is covered only if that treatment is determined to be part of a proven treatment for documented obstructive sleep apnea. Refer to the applicable medical policy to determine if the treatment proposed is proven for obstructive sleep apnea.

2. Oral appliances for snoring with a diagnosis of obstructive sleep apnea are addressed in the Durable Medical Equipment, Orthotics Ostomy Supplies, Medical Supplies and Repairs/Replacements Coverage Determination Guideline.

Coverage Limitations and Exclusions

1. Medical and surgical treatment of snoring is excluded except as described in #1 above.
2. Medical prescribed treatment for snoring (without a diagnosis of obstructive sleep apnea) that includes a Bi-Level or CPAP equipment identified via a clinical review is not a Covered Health Service.
3. Surgical treatments for snoring without a diagnosis of obstructive sleep apnea are not a Covered Health Service.

Examples include, but are not limited to:

- Uvulopalatopharyngoplasty (UPPP)
- Laser-Assisted uvulopalatoplasty (LAUP)
- Somnoplasty
- Submucosal radiofrequency tissue volume reduction

COVERAGE RATIONALE

- I. **Attended full-channel nocturnal polysomnography (NPSG)/laboratory sleep test (LST), performed in a healthcare facility is proven and medically necessary in patients with suspected OSA and one (1) or more of the following indications:**
 - A. **One (1) or more of the following documented co-morbid conditions that would degrade the accuracy of portable monitoring with a home sleep test (HST):**
 1. Significant [chronic pulmonary disease](#) as defined by a forced expiratory volume (FEV1%pred) of <60 (Pelligrino, 2005)
 2. Progressive neuromuscular disease/neurodegenerative disorder [examples include but are not limited to, Parkinson's disease, myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease, history of stroke with persistent neurological sequelae]
 3. Moderate to severe cardiac disease [examples include but are not limited to, congestive heart failure (NYHA class III or IV), uncontrolled cardiac tachyarrhythmia or bradyarrhythmia, pulmonary hypertension]
 4. Body mass index (BMI) >50 ([DeMaria 2007](#), [Blackstone 2009](#))
 5. [Obesity Hypoventilation Syndrome](#) (OHS); **OR**
 - B. **One (1) or more of the following document complex sleep disorders:**
 1. Severe chronic periodic limb movement disorder ([PLMD](#)) (not leg movements associated with another disorder such as sleep disordered breathing)
 2. Restless leg syndrome (RLS)/Ekbom that has not responded to treatment
 3. [Parasomnia](#) with disruptive, violent or potentially injurious sleep behavior suspicious of rapid eye movement (REM) ([RBD](#)) disorder
 4. [Narcolepsy](#) once other causes of excessive sleepiness have been ruled out
 5. History of [central sleep apnea](#); **OR**
 - C. Patient is a child or adolescent (i.e. <18 years of age); **OR**
 - D. Results of previous HST were either:

1. Indeterminate for suspected OSA or upper airway resistance syndrome; **or**
2. Technically inadequate after 2-3 nights; **or**
3. Patient lacks the mobility or dexterity to use HST equipment safely at home; **or**
4. Cognitive impairment such that patient is unable to perform a home sleep study

II. Attended full-channel nocturnal polysomnography (NPSG)/laboratory sleep test (LST), performed in a healthcare facility is unproven and not medically necessary for the evaluation of sleep disorders for any of the following:

- A. Significant chronic lung disease in the absence of symptoms of sleep disorder
- B. [Circadian rhythm disorders](#)
- C. Positive airway pressure (CPAP or Bi-Level) evaluation in patients whose symptoms continue to resolve with CPAP or Bi-Level treatment
- D. Depression
- E. [Insomnia](#)
- F. Epileptic seizures in the absence of symptoms of sleep disorder

There is insufficient published clinical evidence that evaluation of the above disorders with polysomnography (PSG) in the absence of symptoms of sleep disorder leads to better health outcomes.

III. Actigraphy is unproven and not medically necessary for evaluation of sleep related breathing disorders and circadian rhythm disorders.

A review of the evidence does not establish the effectiveness of actigraphy as a standalone tool for diagnosis of obstructive sleep apnea syndrome. In addition, definitive patient selection criteria for the use of actigraphy devices for diagnosis of sleep apnea have not been established. The evidence regarding use of the actigraphy for evaluation of circadian rhythm disorders is of low quality and therefore the clinical utility could not be established.

IV. Multiple sleep latency testing (MSLT) is proven and medically necessary for suspected narcolepsy. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC).

V. Maintenance of wakefulness testing (MWT) is proven and medically necessary for assessment of individuals in whom the inability to remain awake constitutes a safety issue, or for patients with narcolepsy or idiopathic hypersomnia to assess response to treatment with medications. For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 18th edition, 2014, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC).

VI. Multiple sleep latency testing (MSLT) and the maintenance of wakefulness test (MWT) are unproven and not medically necessary for the evaluation and diagnosis of obstructive sleep apnea.

Available published evidence is insufficient to demonstrate improved management of obstructive sleep apnea through the use of MSLT. Published evidence is limited to poorly controlled studies for obstructed sleep apnea.

VII. A split night study with positive airway pressure (PAP) titration performed in an attended sleep laboratory is proven and medically necessary in patients who have met the criteria for attended full channel nocturnal polysomnography studies and if

the diagnosis of OSA can be made within the first 2 hours of recorded sleep, and at least 3 hours of CPAP titration.

VIII. A full night study with positive airway pressure (PAP) titration performed in an attended sleep laboratory is proven and medically necessary in patients who have met the criteria for attended full channel nocturnal polysomnography studies and with confirmed OSA, as determined by either of the following:

A. In patients where the split night was not feasible, as determined by:

1. AHI in the first two hours of testing was less than 20 per hour; or
2. The CPAP titration portion of the original study was insufficient;
 - Less than three hours of titration; or
 - Failure to effectively minimize respiratory events

OR

B. Follow-up titration in patients with persistent or new symptoms despite current CPAP treatment.

Repeat Testing

It may be necessary to perform repeat sleep studies. Where repeat testing is indicated, attended full-channel nocturnal polysomnography (NPSG)/laboratory sleep test (LST) performed in an attended sleep laboratory is proven and medically necessary for persons who meet criteria for attended (LST) above. Where unattended portable monitoring/HST are indicated, an auto-titrating continuous positive airway pressure (APAP) device is an option to determine a fixed CPAP pressure.

DEFINITIONS

Actigraphy: A method of monitoring activity with a portable device or actimeter that can be used while patients are sleeping. Actigraph devices include a small accelerometer that is typically fixed to a patient's wrist to record movement. (AASM, 2007)

Central Apnea: Apnea is defined as a cessation of airflow for at least 10 seconds. Polysomnography (PSG) reveals ≥ 5 central apneas per hour of sleep and a mixed pattern, central apnea $> 50\%$ are significant. The event is central if during apnea there is no effort to breathe. (AASM, 2005) Many sleep studies may show predominantly obstructive sleep apnea with some central events which will also respond to treatment of the OSA. (Eckert, 2007)

Chronic Pulmonary Disease (CPD):

A method of categorizing the severity of lung function impairment based on forced expiratory volume (FEV_1) % pred is provided in the below table. Severity of any spirometric abnormality based on the forced expiratory volume in one second (FEV_1)	
Degree of Severity	FEV_1 % pred
Mild	>70
Moderate	60-69
Moderately severe	50-59
Severe	35-49
Very Severe	<35
% pred: % predicted	

(Pelligrino, 2005)

Circadian Rhythm: An innate daily fluctuation of physiologic or behavior functions, including sleep-awake states, generally tied to the 24-hour daily dark-light cycle. This rhythm sometimes occurs at a measurable different periodicity (e.g. 23 or 25 hours (when light-dark and other time cues are removed. (AASM, 2001)

Disruptive Snoring: As in primary snoring, disruptive snoring includes loud inspiratory or expiratory sounds which disturb bed partners with snoring. The patient is more likely to note sleep disturbance or daytime sleepiness (University of Utah Health Sciences Library). Additionally, disruptive snoring shows markedly increased upper airway resistance where pronounced alterations in timing, amplitude, and synchronization of ribcage/abdominal volume curves as well as inspiratory flattening of their time derivatives (reflects airflow). Similar qualitative changes are seen during simple snoring but to a lesser degree and are not associated with arousals. Characteristic patterns of ribcage/abdominal motion recorded by respiratory inductive plethysmography differentiated breathing in sleep disruptive snoring from simple snoring. (Bloch, 1997)

Epworth Sleepiness Scale (ESS): The Epworth Sleepiness Scale is an 8-question questionnaire which is used to determine the level of a person's daytime sleepiness. The Epworth Sleepiness Scale is based on the patient's assessment of the likelihood of falling asleep in certain situations commonly encountered in daily life. (<http://epworthsleepinessscale.com/about-epworth-sleepiness/>)

Excessive Sleepiness [Somnolence, Hypersomnia, Excessive Daytime Sleepiness (EDS)]: A subjective report of difficulty in maintaining the alert awake state, usually accompanied by a rapid entrance into sleep when the person is sedentary. Excessive sleepiness may be due to an excessively deep or prolonged major sleep episode. It can be quantitatively measured by use of subjectively defined rating scales of sleepiness or physiologically measured by electrophysiological tests such as the multiple sleep latency test (see MSLT). Excessive sleepiness most commonly occurs during the daytime, but it may be present at night in a person, such as a shift worker, who has the major sleep episode during the daytime. (AASM, 2001)

Hypersomnia (Excessive Sleepiness): Excessively deep or prolonged major sleep period, which may be associated with difficulty in awakening. The term is primarily used as a diagnostic term (e.g. idiopathic hypersomnia) and the term excessive sleepiness is preferred to describe the symptom. (AASM, 2001)

Insomnia: Characterized by a complaint of difficulty initiating sleep, maintaining sleep, and/or nonrestorative sleep that causes clinically significant distress or impairment in social, occupational, or other important areas of functioning. (AASM, 2001)

Maintenance of Wakefulness Test (MWT): A series of measurements of the interval from "lights out" to sleep onset that are used in the assessment of an individual's ability to remain awake. Subjects are instructed to try to remain awake in a darkened room while in a semi reclined position. Long latencies to sleep are indicative of the ability to remain awake. This test is most useful for assessing the effects of sleep disorders or of medication upon the ability to remain awake. (AASM, 2001)

Multiple Sleep Latency Test (MSLT): A series of measurements of the interval from "lights out" to sleep onset that is used in the assessment of excessive sleepiness. Subjects are allowed a fixed number of opportunities (typically four or five) to fall asleep during their customary awake period. Excessive sleepiness is characterized by short latencies. Long latencies are helpful in distinguishing physical tiredness or fatigue from true sleepiness. (AASM, 2001)

Medically Necessary: Health care services provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, [Mental Illness,] [mental illness,] substance use

disorder, condition, disease or its symptoms, that are all of the following as determined by us or our designee, within our sole discretion.

- In accordance with *Generally Accepted Standards of Medical Practice*
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for your Sickness, Injury, {Mental Illness,} [mental illness] substance use disorder, disease or its symptoms.
- Not mainly for your convenience or that of your doctor or other health care provider
- Not more costly than an alternative drug, service(s) or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms

Generally Accepted Standards of Medical Practice are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials, or, if not available, observational studies from more than one institution that suggest a causal relationship between the service or treatment and health outcomes.

If no credible scientific evidence is available, then standards that are based on Physician specialty society recommendations or professional standards of care may be considered. We reserve the right to consult expert opinion in determining whether health care services are Medically Necessary. The decision to apply Physician specialty society recommendations, the choice of expert and the determination of when to use any such expert opinion, shall be within our sole discretion. (UHC 2011 COC)

Narcolepsy: A disorder characterized by excessive daytime sleepiness and intermittent manifestations of REM sleep during wakefulness, is the best characterized and studied central hypersomnia. (Wise, 2007)

Obesity Hypoventilation Syndrome (OHS): Refers to the appearance of awake hypercapnia ($\text{PaCO}_2 > 45 \text{ mmHg}$) in the obese patient ($\text{BMI} > 30 \text{ kg/m}^2$) after other causes that could account for awake hypoventilation, such as lung or neuromuscular disease, have been excluded. (Piper, 2011)

Obstructive Apnea: A clear decrease (>50%) from baseline in the amplitude of a valid measure of breathing during sleep lasting at least 10 seconds (note, little difference made between obstructive apnea or hypopnea) (Kushida et al., 2005)

Parasomnia: Parasomnias are undesirable physiologic phenomena that occur predominately during sleep. These sleep related events can be injurious to the patient and others and can produce a serious disruption of sleep-wake schedules and family functioning. Common, uncomplicated, non-injurious parasomnias, such as typical disorders of arousal, nightmares, enuresis, sleeptalking, and bruxism, can usually be diagnosed by clinical evaluation alone. (Kushida et al., 2005) *also see ([RBD](#))

Periodic Limb Movement(s) (PLM): One or more movements which meet the criteria for relatively stereotyped repetitive periodic movements (criteria including number in series, period, duration, amplitude), but not restricted to the sleep state. When enumerated for a given period of observation, usually a full night, the sum is the #PLM. (Hening, 1999)

Periodic Limb Movement Arousal Index (PLMAI): Number of PLMS per hour of sleep associated with an arousal on polysomnography. If enumerated, one or more such movements are PLMA and their sum can be abbreviated as #PLMA. (Hening, 1999)

Periodic Limb Movement Disorder (PLMD): A rapid partial flexion of the foot at the ankle, extension of the big toe, and partial flexion of the knee and hip that occurs during sleep. The movements occur with a periodicity of 20 to 60 seconds in a stereotyped pattern, lasting 0.5 to 5.0 seconds. PLMs are a characteristic feature of the periodic limb movement disorder. (AASM, 2001) The PLMs are not better explained by another current sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance use disorder (e.g., exclude from PLMs counts the movements at the termination of cyclically occurring apneas) (Eckert, 2007)

International Classification of Sleep Disorders (ICSD) Criteria for PLMD Severity and Duration:

Degree of Severity	Description
Mild	Associated with a PLMI of 5-24 per hour and results in mild insomnia or mild sleepiness
Moderate	Associated with a PLMI of 25-49 per hour and results in moderate insomnia or sleepiness
Severe	Associated with a PLMI of greater than 50 per hour or a PLMAI of greater than 25 per hour and results in severe insomnia or sleepiness

Type	Duration
Acute	1 month or less
Subacute	Greater than 1 month but less than 6 months
Chronic	6 months or longer

Periodic Limb Movement Index (PLMI): Number of PLM per hour. Usually refers to number of PLMS per hour of sleep for a whole night's sleep or part of it (e.g. the first third of the night, the sleep period when PLMS in RLS are concentrated). (Hening, 1999)

Polysomnogram: The continuous and simultaneous recording of multiple physiologic variables during sleep, i.e., electroencephalogram, electrooculogram, electromyogram (these are the three basic stage-scoring parameters), electrocardiogram, respiratory air flow, respiratory movements, leg movements, and other electrophysiologic variables. (AASM, 2001)

Rapid eye movement sleep behavior disorder (RBD): Is a parasomnia, first described in cats and later described in human beings by Schenck et al. 1 in 1986. RBD is typically characterized by abnormal or disruptive behaviors emerging during rapid eye movement (R) sleep having the potential to cause injury or sleep disruption such as walking, talking, laughing, shouting, gesturing, grabbing, flailing arms, punching, kicking, and sitting up or leaping from bed (Aurora, 2010)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

CPT [®] Code	Description
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811	Polysomnography; sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by technologist

CPT[®] is a registered trademark of the American Medical Association.

Unproven and Not Medically Necessary Procedure Code

CPT Code	Description
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording).

CPT[®] is a registered trademark of the American Medical Association.

DESCRIPTION OF SERVICES

Obstructive sleep apnea (OSA) is a common disorder affecting at least 2% to 4% of the adult population. Clinically, OSA is defined by the occurrence of daytime sleepiness, loud snoring, witnessed breathing interruptions, or awakenings due to gasping or choking in association with the presence of at least 5 obstructive respiratory events (apneas, hypopneas or respiratory effort related arousals) per hour of sleep.

The diagnosis and severity of OSA must be established before initiating treatment in order to identify those patients at risk of developing the complications of sleep apnea, guide appropriate treatment decisions and to provide a baseline in establishing the effectiveness of subsequent treatment. Diagnostic criteria for OSA are based on clinical signs and symptoms determined during a comprehensive sleep evaluation, which includes a sleep oriented history and physical examination, and findings identified by sleep testing.

Polysomnography (PSG) is the most commonly used test in the diagnosis of sleep related breathing disorders such as obstructive sleep apnea. Polysomnography includes monitoring oxygen saturation, heart rate, chest and abdominal respirations, airflow, eye movements, muscle activity, and sleep parameters [electroencephalography (EEG), electrooculography (EOG), and submental electromyography (EMG)]. Staging of the severity of sleep apnea can be accomplished by utilization of the apnea-hypopnea index (AHI). Respiratory disturbance index (RDI) is another term to stage the severity of sleep apnea which includes the number of apneas and hypopneas, as well as the number of respiratory effort-related arousals per hour of sleep. The term RDI has been defined differently when used with portable monitoring (PM) than when used with PSG. The RDI in PM is the number of apneas plus hypopneas divided by the total recording time rather than total sleep time.

Until recently, diagnosing OSA required an overnight stay in a specialized sleep laboratory, hospital or clinic with a standard laboratory polysomnography (PSG). Demand for testing in the laboratory setting has exceeded the capacity of these clinics. A number of smaller, portable systems that can be used at home have been developed to make testing more convenient and cost-effective. These systems use some of the same devices (respiratory equipment, pulse oximetry equipment, and sensors for movement and position) as the laboratory PSG.

(ECRI, 2013)

For continuous positive airway pressure (CPAP) titration, a split-night study (initial diagnostic PSG followed by CPAP titration during PSG on the same night) is an alternative to one full night of diagnostic PSG followed by a second night of titration.

Auto-titrating continuous positive airway pressure devices (APAP, AutoPap and CPAP) are used to maintain a patent oropharynx to treat patients with obstructive sleep apnea. In contrast to CPAP, which maintains a fixed pressure titrated manually in a sleep center by a sleep technician, APAP devices titrate effective airway pressure throughout the night using an algorithm that responds to physiologic signals. (Kakkar et al., 2007)

In general, although individual APAP devices may differ, APAP devices usually deliver pressures between 4 cm H₂O - 20cm H₂O. (Rinaldi, 2011) The recommended minimum starting CPAP should be 4 cm H₂O. The recommended maximum CPAP should be 15 cm H₂O for patients <12 years, and 20 cm H₂O ≥12 years. (Kushida, 2008)

Actigraphy is a method of monitoring activity with a portable device or actimeter that can be used while patients are sleeping. Actigraph devices include a small accelerometer that is typically fixed to a patient's wrist to record movement.

Multiple sleep latency testing (MSLT) measures daytime sleepiness in patients who are potentially narcoleptic. Multiple sleep latency testing (MSLT) for suspected narcolepsy is used when other sleep disorders have been ruled out by prior polysomnography.

Additional Information

According to the American Academy of Sleep Medicine (AASM) (Epstein et al., 2009) the diagnosis of obstructive sleep apnea (OSA) is confirmed if the number of obstructive events* (apneas, hypopneas + respiratory event related arousals) on polysomnography (PSG) is greater than 15 events/hour in the absence of associated symptoms or greater than 5/hour in a patient who reports any of the following: unintentional sleep episodes during wakefulness; daytime sleepiness; unrefreshing sleep; fatigue; insomnia; waking up breath holding, gasping or choking; or the bed partner describing loud snoring, breathing interruptions, or both during the patient's sleep.

The frequency of obstructive events is reported as an apnea + hypopnea index (AHI) or respiratory disturbance index (RDI). RDI has at times been used synonymously with AHI, but at other times has included the total of apneas, hypopneas, and respiratory effort related arousals (RERAs) per hour of sleep. When a portable monitor is used that does not measure sleep, the RDI refers to the number of apneas plus hypopneas per hour of recording.

OSA severity is defined as

- mild for AHI or RDI ≥ 5 and < 15
- moderate for AHI or RDI ≥ 15 and ≤ 30
- severe for AHI or RDI > 30/hr

The AASM classifies sleep study devices (sometimes referred to as Type or Level) as follows (Collop et al., 2007):

- Type 1: full attended polysomnography (≥ 7 channels) in a laboratory setting
- Type 2: full unattended polysomnography (≥ 7 channels)
- Type 3: limited channel devices (usually using 4–7 channels)
- Type 4: 1 or 2 channels usually using oximetry as 1 of the parameters

This classification system was introduced in 1994 and closely mirrored available Current Procedural Terminology (CPT) codes. However, since that time, devices have been developed

which do not fit well within that classification scheme. In 2011, Collop et al. presented a new classification system for out-of-center (OOC) testing devices that details the type of signals measured by these devices. This proposed system categorizes OOC devices based on measurements of Sleep, Cardiovascular, Oximetry, Position, Effort, and Respiratory (SCOPER) parameters. For additional information see <http://www.aasmnet.org/Resources/PracticeParameters/Outofcenter.pdf>. Accessed May 8, 2014.

Multiple-Night Home Sleep Testing vs One-Night Home Sleep Testing:

Results of clinical studies demonstrate that night-to night variability in home sleep testing is comparable to laboratory-based polysomnography. The reported respiratory disturbance index (RDI) variability is small and a single night testing can correctly diagnose obstructive sleep apnea (OSA) in the majority of patients with a high pretest-probability of OSA. Reported data loss for unattended portable monitoring ranges from 3%-33%. For a new device with an audible alarm only 2% of sleep testing resulted in insufficient data. In instances where a technical failure occurs, a second night home sleep test may be warranted. If home sleep testing in the high-risk patient is normal or technically inadequate the AASM recommends in-laboratory polysomnography. (Collop et al., 2007)

Severity Classification of Lung Function:

A method of categorizing the severity of lung function impairment based on forced expiratory volume (FEV₁) % pred is provided in the below table.

Severity of any spirometric abnormality based on the forced expiratory volume in one second (FEV₁)	
Degree of Severity	FEV₁ % pred
Mild	>70
Moderate	60-69
Moderately severe	50-59
Severe	35-49
Very Severe	<35
<i>% pred: % predicted</i>	

(Pellegrino, 2005)

International Classification of Sleep Disorders (ICSD) Criteria for PLMD Severity and Duration:

Degree of Severity	Description
Mild	Associated with a PLMI of 5-24 per hour and results in mild insomnia or mild sleepiness
Moderate	Associated with a PLMI of 25-49 per hour and results in moderate insomnia or sleepiness
Severe	Associated with a PLMI of greater than 50 per hour or a PLMAI of greater than 25 per hour and results in severe insomnia or sleepiness

Type	Duration
Acute	1 month or less
Subacute	Greater than 1 month but less than 6 months
Chronic	6 months or longer

(Hening, 1999)

CLINICAL EVIDENCE

Flemons et al. (2003) did a comprehensive review of the published literature on portable monitors for PSG. The review was cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. Flemons et al. concluded that the use of portable monitoring as an initial diagnostic tool for selected patients may reduce costs because patients with positive results could go ahead with CPAP titration studies and patients with negative results might not require additional testing.

In 2011, Collop et al. reported the results of a technology evaluation of sleep testing devices used in the out-of-center (OOC) setting performed by an AASM task force. Only peer-reviewed English literature and devices measuring 2 or more bioparameters were included in the analysis. Studies evaluating 20 different devices or models (e.g. ARES, ApneaLink, Embletta, Novasom QSG/Bedbug/Silent Night, SNAP, Stardust II, Watch-PAT) were reviewed. Devices were judged on whether or not they can produce a positive likelihood ratio (LR+) of at least 5 and a sensitivity of at least 0.825 at an in-lab AHI of at least 5. The authors concluded that:

- The literature is currently inadequate to state with confidence that a thermistor alone without any effort sensor is adequate to diagnose OSA;
- If a thermal sensing device is used as the only measure of respiration, 2 effort belts are required as part of the montage and piezoelectric belts are acceptable in this context;
- Nasal pressure can be an adequate measurement of respiration with no effort measure with the caveat that this may be device specific;
- Nasal pressure may be used in combination with either 2 piezoelectric or respiratory inductance plethysmographic (RIP) belts (but not 1 piezoelectric belt);
- There is insufficient evidence to state that both nasal pressure and thermistor are required to adequately diagnose OSA;
- With respect to alternative devices for diagnosing OSA, the data indicate that
 - Peripheral arterial tonometry (PAT) devices are adequate for the proposed use;
 - The device based on cardiac signals shows promise, but more study is required as it has not been tested in the home setting;
 - For the device based on end-tidal CO₂ (ETCO₂), it appears to be adequate for a hospital population; and for devices utilizing acoustic signals;
 - The data are insufficient to determine whether the use of acoustic signals with other signals as a substitute for airflow is adequate to diagnose OSA.

For details regarding specific devices see full text article at:

<http://www.aasmnet.org/Resources/PracticeParameters/Outofcenter.pdf>

Single-Night vs. Multiple-Night Home Sleep Testing

A single-night polysomnography is usually considered adequate to determine if OSA is present and the degree of the disorder. Since the PSG is considered the reference standard, the reliability and technical accuracy of PSG is generally accepted without question. However, PSG, even when accurately measured, recorded, and analyzed, may misclassify patients based upon night-to-night variability in measured parameters. For example, estimates of the sensitivity of one night of PSG to detect an AHI > 5 in patients with OSA range between 75 to 88%. (Kushida et al., 2005)

Levendowski et al (2009) published the first study that investigated the variability of AHI obtained by PSG and by in-home portable recording in 37 untreated mild to moderate OSA patients at a four- to six-month interval. The in-home studies were performed with Apnea Risk Evaluation System (AREST™) Unicorder. When comparing the test-retest AHI and apnea index (AI), the in-home results were more highly correlated ($r = 0.65$ and 0.68) than the comparable PSG results ($r = 0.56$ and 0.58). The in-home results provided approximately 50% less test-retest variability than

the comparable polysomnography AHI and AI values. Both the overall polysomnography AHI and AI showed a substantial bias toward increased severity upon retest (8 and 6 events/hr respectively) while the in-home bias was essentially zero. The in-home percentage of time supine showed a better correlation compared to PSG ($r = 0.72$ vs. 0.43). Patients biased toward more time supine during the initial PSG. No trends in time supine for in-home studies were noted.

Night-to-night variability in home sleep testing was previously assessed in a number of clinical studies. Most of these studies involved a small number of patients.

Redline et al. (1991), Quan et al. (2002; erratum 2009) and Davidson et al. (2003) found no evidence of a statistically significant difference in RDI between nights 1 and 2, suggesting that there was no significant respiratory first-night effect.

Fietze et al. (2004) investigated the night-to-night variability and diagnostic accuracy of the oxygen desaturation index (ODI) in 35 patients using the portable recording device MESAM-IV at home during 7 consecutive. The authors found that although the reliability of the ODI was adequate, the probability of placing the patient in the wrong severity category (ODI $<$ or $=15$ or ODI >15) when only one single recording was taken is 14.4%. The authors concluded that in most OSA patients, oxygen desaturation index variability is rather small, and screening could be reliably based on single 1-night recordings.

The largest study by Stepnowsky et al. (2004) examined the nightly variability of AHI in a retrospective comparison of 3 sequential nights of testing performed in the home in 1091 patients who were referred for diagnostic testing of sleep-disordered breathing (SDB). Based on night 1, approximately 90% of patients were classified consistently with "AHI-high" (the highest AHI measured across the 3 nights) using an AHI threshold of 5. However, 10% were misclassified on night 1 relative to the highest AHI level. The authors concluded that there is little, if any, significant nightly change in SDB in the home environment.

The results of these clinical studies demonstrate, that night-to night variability in home sleep testing is comparable to laboratory-based polysomnography and that a single night testing can correctly diagnose OSA in the majority of patients with a high pretest-probability of OSA.

Home-based versus In-laboratory Diagnostic and Therapeutic Pathway

Recent comparative effectiveness research studies have shown that clinical outcomes of patients with a high pretest probability for obstructive sleep apnea who receive ambulatory management using portable-monitor testing have similar functional outcomes and adherence to continuous positive airway pressure treatment, compared to patients managed with in laboratory polysomnography. (Kuna, 2010)

Mulgrew et al. (2007) randomly assigned 68 high-risk patients identified by a diagnostic algorithm to polysomnography (PSG) or ambulatory titration by using a combination of auto-CPAP and overnight oximetry. After 3 months, there were no differences in AHI on CPAP between the PSG and ambulatory groups, or in the ESS score, or quality of life. Adherence to CPAP therapy was better in the ambulatory group than in the PSG group. Results of another randomized controlled multicenter non inferiority study by Antic et al. (2009) that compared nurse-led home diagnosis and CPAP therapy with physician-led current best practice in OSA management in 195 patients complement and extend the findings of Mulgrew et al. There were no differences between both groups in ESS score and CPAP adherence at 3 months. Within-trial costs were significantly less in the simplified home model. Cost-effectiveness of home APAP titration compared to manual laboratory titration was also confirmed McArdle et al. (2011). In this randomized controlled study involving 249 patients with moderate to severe OSA without serious co-morbidities, outcomes at one month indicated that average nightly CPAP use, subjective sleepiness, quality of life, cognitive function and polysomnographic outcomes were similar among the per-protocol groups.

Berry et al. (2008) compared a clinical pathway using portable monitoring (PM) for diagnosis and unattended APAP for selecting an effective CPAP with another pathway using PSG for diagnosis

and treatment of OSA in a randomized parallel group study involving 106 patients with a high likelihood of having OSA. After 6 weeks of treatment 40 patients in the PM-APAP group and 39 in the PSG arm were using CPAP treatment ($P = NS$). The mean nightly adherence, decrease in Epworth Sleepiness Scale score, improvement in functional score, and CPAP satisfaction did not differ between the groups.

In a randomized controlled study involving 102 patients with suspected OSA, Skomro et al. (2010) compared a home-based diagnostic and therapeutic strategy for OSA with in-laboratory PSG and CPAP titration (using mostly split-night protocol). Subjects in the home monitoring arm underwent 1 night of level three testing (Embletta) followed by 1 week of auto-CPAP therapy (Auto-Set) and 3 weeks of fixed-pressure CPAP based on the 95% pressure derived from the auto-CPAP device. After 4 weeks of CPAP therapy, there were no significant differences in daytime sleepiness (ESS), sleep quality, quality of life, blood pressure, and CPAP adherence.

In another randomized controlled non-inferiority study Kuna et al. (2011) compared functional outcome and treatment adherence in veterans with suspected OSA who received ambulatory versus in-laboratory testing for OSA. Home testing consisted of a type 3 portable monitor recording (Embletta) followed by at least three nights using an APAP device (RemStar Auto). In-laboratory testing was performed as a split-night PSG if clinically indicated. Of the 296 subjects enrolled, 260 (88%) were diagnosed with OSA, and 213 (75%) were initiated on CPAP. At 3 months of CPAP treatment the functional outcome score improved 1.74 ± 2.81 in the home group and 1.85 ± 2.46 in the in-laboratory group. CPAP adherence was 3.5 ± 2.5 hours/day in the home group and 2.9 ± 2.3 hours/day in the in-laboratory group ($P = 0.08$).

Lettieri et al. (2011) conducted an observational cohort study including 210 patients with OSA that were grouped into one of three pathways based on the type and location of their diagnostic and titration. Group 1 underwent unattended, type III home diagnostic (Stardust II) and unattended home APAP titrations (Respironics System One); group 2 underwent in-laboratory, type I diagnostic and continuous PAP titration studies; group 3 underwent type I diagnostic and APAP titration studies. Group 1 was primarily managed and educated in a primary care clinic, whereas groups 2 and 3 received extensive education in an academic sleep medicine center. The authors found that type of study and location of care did not affect PAP adherence. Patients in all three pathways demonstrated equivalent use of PAP despite differences in polysomnographic procedures, clinical education, and follow-up.

A single-blind randomized controlled trial with 200 CPAP-naive patients found home-based APAP to be as effective as automatic in-laboratory titrations in initiating treatment for OSA at 3-month follow-up with no significant difference in CPAP use, Epworth Sleepiness Scale score, OSLER, Functional Outcomes of Sleep Questionnaire, or SF-36 between the groups. (Cross et al., 2006)

Another multicenter randomized controlled prospective study involving 35 patients with newly diagnosed severe obstructive OSA has concluded that OSA can be effectively and reliably treated with APAP at home, with reduced time from diagnosis to treatment, and at a lower cost compared with in-laboratory titration. (Planes et al., 2003)

In a randomized, single-blinded crossover trial Bakker et al. (2011) compared the effectiveness of CPAP and APAP (S8 Autoset II® , ResMed) over a period of six nights at home, separated by a four-night washout in 12 morbidly obese OSA patients requiring high therapeutic pressure (AHI 75.8 ± 32.7 , body mass index $49.9 \pm 5.2 \text{ kg m}^{-2}$, mean pressure $16.4 \text{ cmH}_2\text{O}$) without significant co-morbid disease. Both therapies substantially reduced the AHI (APAP 9.8 ± 9.5 and CPAP 7.3 ± 6.6 events h^{-1} ; $P=0.35$), but residual PSG measures of disease (AHI >5) were common. APAP delivered a significantly lower 95th percentile pressure averaged over the home-use arm than CPAP (14.2 ± 2.7 and $16.1 \pm 1.8 \text{ cmH}_2\text{O}$, respectively, $P=0.02$). The authors concluded that this study supports the use of either APAP or manually titrated CPAP in this specific population. Since the APAP-scored AHI significantly overestimated the level of residual disease compared with the

laboratory-scored AHI the authors recommend objective assessment by sleep study if the APAP indicates a high level of residual disease.

McArdle et al. (2000) compared long-term outcomes in all 49 (46 accepting CPAP) patients prescribed split-night studies with those in full-night patients, matched 1:2 using an apnea/hypopnea index (AHI) of +/-15% and Epworth score of +/-3 units. There were no differences between the groups in long-term CPAP use, median nightly CPAP use, post-treatment Epworth scores and frequency of nursing interventions/clinic visits required. The median time from referral to treatment was less for the split-night patients than for full-night patients.

Khawaja et al. (2010) reviewed 114 consecutive full-night PSGs (FN-PSG) on subjects with OSA and compared the AHI from the first 2 hours (2 hr-AHI) and 3 hours (3 hr-AHI) of sleep with the "gold standard" AHI from FN-PSG (FN-AHI), considering OSA present if FN-AHI > or = 5. The authors found that the AHI derived from the first 2 or 3 hours of sleep is of sufficient diagnostic accuracy to rule-in OSA at an AHI threshold of 5 in patients suspected of having OSA. This study suggests that the current recommended threshold for split-night studies (AHI > or = 20 to 40) may be revised to a lower number, allowing for more efficient use of resources.

Collen et al. (2010) evaluated 400 consecutive patients presenting for follow-up 4-6 weeks after initiating CPAP therapy. Among the patients, 267 and 133 underwent split- and dual-night studies, respectively. The mean number of days between diagnosis and titration in the dual-night group was 80.5 days. There was no difference in therapeutic adherence between groups as measured by percentage of nights used (78.7% vs 77.5%; $p = 0.42$), hours per night used (3.9 vs 3.9; $p = 0.95$), or percentage of patients using continuous positive airway pressure for >4 hours per night for >70% of nights (52.9% vs 51.8%; $p = 0.81$). There was no difference in use after adjusting for severity of disease. The authors concluded that split-night polysomnography does not adversely affect short-term continuous positive airway pressure adherence in patients with obstructive sleep apnea.

Gao et al. (2011) conducted a systematic review to evaluate the effect of automatic titration compared to manual titration prior to CPAP treatment in OSA patients. The authors evaluated APAP in identifying an effective pressure and the improvement of AHI and somnolence, change in sleep quality, and the acceptance and compliance of CPAP treatment compared to manual titration. Ten randomized controlled trials (849 patients) met the inclusion criteria. Studies were pooled to yield odds ratios (OR) or mean differences (MD) with 95% confidence intervals (CI). Automatic titration improved the AHI (MD=0.03/h, 95% CI=4.48-4.53) and Epworth sleepiness scale (SMD=0.02, 95% CI=0.34-0.31) as effectively as manual titration. There was no difference in sleep architecture between auto titration and manual titration. There was also no difference in acceptance of CPAP treatment or compliance with treatment. The authors concluded that automatic titration is as effective as standard manual titration in terms of improvement in AHI, somnolence, and sleep quality, as well as acceptance and adherence to CPAP.

Actigraphy

In 2008, Hayes assessed a number of studies evaluating specific actigraphy recording devices for diagnose of obstructive sleep apnea in adults between 1986 and 2008. Many of the studies evaluated the actigraphy device in the sleep laboratory, simultaneously obtaining measurements using the standard PSG. A few studies evaluated actigraphy performed on patients in their homes, and in other studies, both simultaneous recording in the sleep laboratory and a separate home study were performed. Hayes found that many of the actigraphy devices have not been validated sufficiently in a home setting and it is unclear whether results obtained in the laboratory can be reproduced in a less controlled environment. Additionally, no direct comparisons of the various actigraphy devices for the specific purpose of diagnosing obstructive sleep apnea syndrome were found in the published literature, and therefore, it is difficult to draw conclusions about their relative efficacies for this use. Hayes concluded that the evidence to date does not establish the effectiveness of actigraphy as a stand-alone tool for diagnosis of obstructive sleep

apnea syndrome. Update searches from 2009, 2010, 2011 and 2012 indicated no anticipated impact on the conclusions of the original report. (Hayes, 2008; last updated 2012)

There is very limited evidence regarding the accuracy of actigraphy for the diagnosis of circadian rhythm sleep disorders (CRSDs). The few available studies involved different types of CRSDs and different patient populations, as well as different actigraphy devices and reference standards, making it difficult to compare results across studies. None of the studies evaluated the impact of actigraphy on patient management or health outcomes, and therefore the clinical utility of this technology cannot be adequately assessed. Actigraphy was not associated with any safety issues. Overall, the evidence to date does not establish the effectiveness of actigraphy as a stand-alone tool for diagnosis of CRSDs. Update searches from 2011, 2012 and 2013 found some newly published studies. However, a review of these have no impact on the original report and do not change previous conclusions. (Hayes, 2010; last updated 2013)

Professional Societies

American Academy of Sleep Medicine (AASM)

In their 2005 practice parameters for the indications for polysomnography and related procedures, the AASM considers polysomnography the "gold standard" for the evaluation of sleep and sleep related breathing. They caution, however, that PSG even when accurately measured, recorded, and analyzed, may misclassify patients based upon night-to-night variability in measured parameters, the use of different types of leads that may lead to over- or underestimation of events (e.g., use of thermistors vs. nasal cannula), and the vagaries of the clinical definitions of disease.

The AASM also stated that a split-night study (initial diagnostic PSG followed by continuous positive airway pressure titration on the same night) is an alternative to one full night of diagnostic PSG. The split-night study may be performed if an AHI \geq 40/hr is documented during 2 hours of a diagnostic study but may be considered for an AHI of 20-40/hr based on clinical judgment. In patients where there is a strong suspicion of OSA, if other causes for symptoms have been excluded, a second diagnostic overnight PSG may be necessary to diagnose the disorder. (Kushida et al., 2005)

In December 2007, the AASM released updated clinical guidelines on the use of unattended portable monitors, essentially, at-home use, for diagnosing OSA in adults (Collop, 2007). In these guidelines, which consisted of a review of the evidence, the AASM concluded:

- Unattended portable monitoring for the diagnosis of OSA should be performed only in conjunction with a comprehensive sleep evaluation.
- Clinical sleep evaluations using portable monitoring must be supervised by a practitioner with board certification in sleep medicine or an individual who fulfills the eligibility criteria for the sleep medicine certification examination.
- Portable monitoring should not be used in the absence of a complete and comprehensive sleep evaluation.
- Portable monitoring may be used as an alternative to standard PSG for diagnosing OSA in patients with a high pretest probability of moderate-to-severe OSA.
- Portable monitoring is not appropriate for diagnosis of OSA in patients with significant comorbidity that may degrade the accuracy of the test (e.g., congestive heart failure). It is also not appropriate for diagnosis of OSA in patients with coexisting sleep disorders of other types (e.g., periodic limb movement disorder).
- Portable monitoring may be indicated for the diagnosis of OSA in patients for whom in-laboratory PSG is not possible by virtue of immobility, safety, or critical illness.
- Portable monitoring may be indicated to monitor the response to non-CPAP treatments for OSA.
- At a minimum, the portable monitor must record airflow, respiratory effort, and blood oxygenation.

- Actigraphy is not a sufficiently accurate substitute measure of sleep time to recommend its routine use.
- If portable monitoring in the high-risk patient is negative or indeterminate, in-laboratory PSG is recommended.
- Portable sleep monitoring is not recommended for children.

The 2009 updated AASM clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults states that MSLT is not routinely indicated in the initial evaluation and diagnosis of OSA or in an assessment of change following treatment with nasal CPAP. However, if excessive sleepiness continues despite optimal treatment, the patient may require an evaluation for possible narcolepsy, including MSLT. (Epstein, 2009)

A practice parameter by Littner et al. (2005), regarding the clinical use of the multiple sleep latency testing and the maintenance of wakefulness test concluded:

1. The MSLT is indicated as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis.
2. The MSLT may be indicated as part of the evaluation of patients with suspected idiopathic hypersomnia to help differentiate idiopathic hypersomnia from narcolepsy.
3. The MSLT is not routinely indicated in the initial evaluation and diagnosis of obstructive sleep apnea syndrome or in assessment of change following treatment with nasal continuous positive airway pressure (CPAP).
4. The MSLT is not routinely indicated for evaluation of sleepiness in medical and neurological disorders (other than narcolepsy), insomnia, or circadian rhythm disorders
5. Repeat MSLT testing may be indicated in the following situations:
 - a. When the initial test is affected by extraneous circumstances or when appropriate study conditions were not present during initial testing
 - b. When ambiguous or uninterpretable findings are present
 - c. When the patient is suspected to have narcolepsy but earlier MSLT evaluation(s) did not provide polygraphic confirmation

Agency for Healthcare Research and Quality (AHRQ)

In 2007, the AHRQ published a technology assessment on home diagnosis of obstructive sleep apnea-hypopnea syndrome based on the review of 95 clinical studies. (Trikalinos, 2007) The authors concluded that AHI measurements from portable monitors and facility-based PSG are not interchangeable, especially in the higher end of the AHI spectrum. Substantial differences may be seen between type II monitors and facility-based PSG, and even larger differences cannot be excluded for type III monitors, and more so for type IV monitors. Based on limited data, type II monitors may identify AHI suggestive of OSAHS with high positive likelihood ratios (>10) and low negative likelihood ratios (<0.1) in sleep labs and at home. Type III monitors may have the ability to predict AHI suggestive of OSAHS with high positive likelihood ratios and low negative likelihood ratios for various AHI cutoffs in laboratory-based PSG, especially when manual scoring is used. The ability of type III monitors to predict AHI suggestive of OSAHS appears to be better in studies conducted in the specialized sleep unit compared to studies in the home setting. Studies of type IV monitors that record at least three bioparameters showed high positive likelihood ratios and low negative likelihood ratios. Studies of type IV monitors that record one or two bioparameters also had high positive likelihood ratios and low negative likelihood ratios. Conditions that effect sleep (e.g., cardiac insufficiency, COPD, obesity hypoventilation syndrome, or periodic limb movements in sleep or restless leg syndrome) may be misdiagnosed as OSAHS by monitors that do not record channels necessary for differential diagnosis. Manual scoring or manual editing of automated scoring appears to have better agreement with facility-based PSG compared to automated scoring in the studies that assessed this factor. In addition, automated scoring algorithms differ among the devices, and their ability to recognize respiratory events may vary.

In 2011, the AHRQ published a Comparative Effectiveness Review titled *Diagnosis and Treatment of Obstructive Sleep Apnea in Adults*. (Balk et al., 2011) The key questions focus on

OSA screening and diagnosis, treatments, associations between AHI and clinical outcomes, and predictors of treatment compliance.

Findings:

- The strength of evidence is moderate that Type III and Type IV monitors may have the ability to accurately predict AHI suggestive of OSA with high positive likelihood ratios and low negative likelihood ratios for various AHI cutoffs in PSG. Type III monitors perform better than Type IV monitors at AHI cutoffs of 5, 10, and 15 events/hr. Large differences compared with in-laboratory PSG cannot be excluded for all portable monitors. The evidence is insufficient to adequately compare specific monitors to each other.
- The strength of evidence is low that the Berlin Questionnaire is able to prescreen patients with OSA with moderate accuracy. There is insufficient evidence to evaluate other questionnaires or clinical prediction rules.
- No study adequately addressed phased testing for OSA.
- There was insufficient evidence on routine preoperative testing for OSA.
- High strength of evidence indicates an AHI >30 events/hr is an independent predictor of death; lesser evidence for other outcomes.
- There is moderate evidence that CPAP is an effective treatment for OSA. There is also moderate evidence that autotitrating and fixed CPAP have similar effects. There is insufficient evidence regarding comparisons of other CPAP devices.
- The strength of evidence is moderate that oral devices are effective treatment for OSA. There is moderate evidence that CPAP is superior to oral devices.
- There was insufficient trial evidence regarding the relative value of most other OSA interventions, including surgery.
- The strength of evidence is high and moderate, respectively, that AHI and Epworth Sleepiness Scale are independent predictors of CPAP compliance.
- There is low evidence that some treatments improve CPAP compliance.

The authors concluded that portable monitors and questionnaires may be effective screening tools, but assessments with clinical outcomes are necessary to prove their value over polysomnography. CPAP is highly effective in minimizing AHI and improving sleepiness. Oral devices are also effective, although not as effective as CPAP. Other interventions, including those to improve compliance, have not been adequately tested.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Systems to record and analyze polysomnography information are regulated by the FDA as Class II Devices under the 510(k) premarketing notification process (product GWQ). A complete list of such devices that have completed this requirement is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. Accessed April 9, 2014.

The FDA has approved more than 100 home sleep testing devices as ventilatory effort recorder (product code MNR) via the 510(k) process. For additional information see FDA webpage at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. April 9, 2014.

Actigraphy devices are classified as electroencephalograph devices (product code GWQ)

Examples include:

- [K040554](#): ActiGraph (Manufacturing Technology Inc.) approved on July 16, 2004.
- [K011430](#): Actiware-PLMS Activity Recording Device (Mini Mitter Co. Inc.) approved on May 31, 2001.
- [K992410](#): ActiTrac (Individual Monitoring Systems Inc.) approved on October 15, 1999 .
- [K983533](#): Actiwatch® (Mini Mitter Co. Inc.) approved on March 20, 1999.

The FDA has cleared for marketing a number of different APAP devices via the 510(k) process. These devices vary with respect to the physiologic variables that are monitored to determine

pressure changes and the decision paths used to determine whether and how much to increase or decrease pressure. A complete list of such devices is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. Search for product code: BZD (ventilator, non-continuous (respirator)). Note: CPAP and auto-CPAP devices are classified under the above product code (which also includes ventilator devices that are not used to deliver CPAP).

510(k) data base was accessed on May 8, 2014.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare covers polysomnography testing when criteria are met. Refer the National Coverage Determinations (NCD) for [Sleep Testing for Obstructive Sleep Apnea \(OSA\)](#).

Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for [Outpatient Sleep Studies](#), [Polysomnography](#), [Polysomnography and Other Sleep Studies](#), [Polysomnography and Sleep Studies](#), [Polysomnography and Sleep Studies for Testing Sleep and Respiratory Disorders](#), [Polysomnography and Sleep Testing](#) and [Sleep Disorders Testing](#). (Accessed April 9, 2014)

REFERENCES

American Academy of Sleep Medicine (AASM), International Classification of Sleep Disorders – Third Edition (ICSD-3). 2014

American Academy of Sleep Medicine (AASM). Obstructive Sleep Apnea. Website: Available at: <http://www.aasmnet.org/Resources/FactSheets/SleepApnea.pdf>. 2008. Accessed May 20, 2014.

American Academy of Sleep Medicine (AASM). Standards for Accreditation of Out of Center Sleep Testing (OCST) in Adult Patients. Available at: <http://www.aasmnet.org/ocststandards.aspx>. Accessed May 20, 2014.

Antic NA, Buchan C, Esterman A, et al. A randomized controlled trial of nurse-led care for symptomatic moderate-severe obstructive sleep apnea. *Am J Respir Crit Care Med*. 2009 Mar 15;179(6):501-8..

Aurora N, Kristo D, Bista S, et al, The Treatment of Restless Legs Syndrome and Periodic Limb Movement Disorder in Adults—An Update for 2012: Practice Parameters with an Evidence-Based Systematic Review and Meta-Analyses. *SLEEP* 2012;35(8):1039-1062.

Aurora N, Zak RS. Best Practice Guide for the Treatment of REM Sleep Behavior Disorder (RBD). *Journal of Clinical Sleep Medicine*, Vol.6, No. 1, 2010.

Bakker J, Campbell A, Neill A. Randomised controlled trial of auto-adjusting positive airway pressure in morbidly obese patients requiring high therapeutic pressure delivery. *J Sleep Res*. 2011 Mar;20(1 Pt 2):233-40.

Balk EM, Moorthy D, Obadan NO, et al. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32. (Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-100551). AHRQ Publication No. 11 EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality. July 2011. Available at: http://www.effectivehealthcare.ahrq.gov/ehc/products/117/683/CER32_SleepApnea_FinalReview_201108.pdf. Accessed May 20, 2014.

Berry RB, Hill G, Thompson L, et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. *Sleep*. 2008 Oct 1;

31(10):1423-31. Available at:
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2572748/?tool=pubmed>. Accessed May 20, 2014.

Blackstone RP, Cortés MC. Metabolic acuity score: effect on major complications after bariatric surgery. *Surg Obes Relat Dis*. 2010 May-Jun;6(3):267-73. Epub 2009 Sep 26.

Bloch KE, Li Y, Sackner MA, et al. Breathing pattern during sleep disruptive snoring. *Eur Respir J* 1997; 10: 576–586. Available at: <http://erj.ersjournals.com/content/10/3/576.full.pdf>. Accessed May 20, 2014.

Collop NA, Anderson WM, Boehlecke B, et al. Portable Monitoring Task Force of the American Academy of Sleep Medicine. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med*. 2007; 3(7). Available at: <http://www.aasmnet.org/jcsm/AcceptedPapers/PMProof.pdf>. Accessed May 20, 2014.

Collop NA, Tracy SL, Kapur V, et al. Obstructive Sleep Apnea Devices for Out-Of-Center (OOC) Testing: Technology Evaluation. *J Clin Sleep Med*. 2011 Oct 15;7(5):531-48. Available at: <http://www.aasmnet.org/Resources/PracticeParameters/Outofcenter.pdf>. Accessed May 20, 2014.

Collen J, Holley A, Lettieri C, et al. The impact of split-night versus traditional sleep studies on CPAP compliance. *Sleep Breath*. 2010 Jun; 14(2):93-9. Epub 2009 Aug 28.

Cross MD, Vennelle M, Engleman HM, et al. Comparison of CPAP titration at home or the sleep laboratory in the sleep apnea hypopnea syndrome. *Sleep*. 2006 Nov 1; 29(11):1451-5.

Davidson TM, Gehrman P, Ferreyra H. Lack of night-to-night variability of sleep-disordered breathing measured during home monitoring. *Ear Nose Throat J*. 2003 Feb; 82(2):135-8. PubMed PMID: 12619471

DeMaria E, Murr M, Byrne K, et al. Validation of the Obesity Surgery Mortality Risk Score in a Multicenter Study. *Ann Surg*. 2007; 246(4):578-584.

Eckert D, Jordan A, Merchia P, et al. Central Sleep Apnea: Pathophysiology and Treatment. *Chest*. 2007;131(2):595-607.

ECRI Institute Health Technology Assessment Information Service (HTAIS). Hotline Response. Autotitrating versus Fixed Continuous Positive Airway Pressure for Treating Obstructive Sleep Apnea. Published May 28, 2013.

ECRI Institute: Health Technology Assessment Information Service (HTAIS). Hotline Response. Ambulatory Sleep Apnea Monitors for Diagnosing Obstructive Sleep Apnea. July 16, 2013.

Epstein LJ, Kristo D, Strollo PJ Jr, et al. Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009 Jun 15; 5(3):263-76. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699173/pdf/jcsm.5.3.263.pdf>. Accessed May 22, 2014.

Fietze I, Dingli K, Diefenbach K, et al. Night-to-night variation of the oxygen desaturation index in sleep apnoea syndrome. *Eur Respir J* 2004; 24:987-93. Available at: <http://erj.ersjournals.com/content/24/6/987.long>. Accessed May 22, 2014.

Flemons WW, Littner MR, Rowley JA, et al. Home diagnosis of sleep apnea: a systematic review of the literature. *Chest*. October 2003; 124(4):1543-1579.

Garcia-Borreguero D, Ferini-Strambi L, Kohnen R, et al. European guidelines on management of restless legs syndrome: report of a joint task force by the European Federation of Neurological Societies, the European Neurological Society and the European Sleep Research Society. *Eur J Neurol*. 2012 Nov;19(11):1385-96.

Gao W, Jin Y, Wang Y, Sun M, Cehn B, Zhou N, Deng Y. Is automatic CPAP titration as effective as manual CPAP titration in OSAHS patients? A meta-analysis. *Sleep Breath*. 2012 Jun;16(2):329-40. Epub 2011 Feb 24

Global Initiative for Chronic Obstructive Lung Disease (GOLD), Inc. Global Strategy for the Diagnosis, Management, and prevention of Chronic Obstructive Pulmonary Disease (Revised 2011). Available at: http://www.goldcopd.org/uploads/users/files/GOLD_Report_2011_Feb21.pdf. Accessed May 22, 2014.

Hayes, Inc. Hayes Medical Technology Directory. Actigraphy for Diagnosis of Obstructive Sleep Apnea in Adults. Lansdale, PA: Hayes, Inc.; April 17, 2008. Last updated June 28, 2012. Report archived as outdated May 17, 2013.

Hayes, Inc. Medical Technology Directory. Actigraphy for Diagnosis of Circadian Rhythm Sleep Disorders. Landsdale, PA: Hayes, Inc; November 17, 2010. Last updated (annual review) November 2013.

Hayes, Inc. Medical Technology Directory. Home Sleep Studies for Diagnosis of Obstructive Sleep Apnea Syndrome in Patients Younger Than 18 Years of Age. October 5, 2012. Last updated (annual review) October 29, 2013.

Hening W, Allen R, Earley C. The Treatment of Restless Legs Syndrome and Periodic Limb Movement Disorder. *Sleep*, Vol. 22, No. 7, 1999

Kakkar RK, Berry RB. Positive airway pressure treatment for obstructive sleep apnea. *Chest* 2007; 132(3):1057-72.

Khawaja IS, Olson EJ, van der Walt C, et al. Diagnostic accuracy of split-night polysomnograms. *J Clin Sleep Med*. 2010 Aug 15; 6(4):357-62.

Kuna ST, Gurubhagavatula I, Maislin G, et al. Noninferiority of functional outcome in ambulatory management of obstructive sleep apnea. *Am J Respir Crit Care Med*. 2011 May 1;183(9):1238-44. Epub 2011 Jan 21.

Kuna ST. Portable-monitor testing: an alternative strategy for managing patients with obstructive sleep apnea. *Respir Care*. 2010 Sep; 55 (9):1196-215. Available at: <http://www.rcjournal.com/contents/09.10/09.10.1196.pdf>. Accessed May 22, 2014

Kushida CA, Chediak A, Berry RB, et al., Positive Airway Pressure Titration Task Force of the American Academy of Sleep Medicine. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. *J Clin Sleep Med* 2008;4(2):157–171.

Kushida CA, Littner MR, Morgenthaler T, et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. *Sleep*. 2005 Apr 1; 28 (4):499-521. Available at: http://www.aasmnet.org/Resources/PracticeParameters/PP_Polysomnography.pdf. Accessed May 22, 2014.

Lettieri CF, Lettieri CJ, Carter K. Does home sleep testing impair continuous positive airway pressure adherence in patients with obstructive sleep apnea? *Chest*. 2011 Apr;139(4):849-54. Epub 2011 Feb 3.

Levendowski D, Steward D, Woodson BT, et al. The impact of obstructive sleep apnea variability measured in-lab versus in-home on sample size calculations. *Int Arch Med*. 2009 Jan 2; 2 (1):2.

Littner MR, Kushida C, Wise M, et al. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. *Sleep* 2005 Jan 1; 28(1):113-21. Available at: http://www.aasmnet.org/Resources/PracticeParameters/PP_MSLTMWT.pdf Accessed May 22, 2014.

McArdle N, Singh B, Murphy M, et al. Continuous positive airway pressure titration for obstructive sleep apnoea: automatic versus manual titration. *Thorax*. 2010 Jul;65(7):606-11.

McArdle N, Grove A, Devereux G, et al. Split-night versus full-night studies for sleep apnoea/hypopnoea syndrome. *Eur Respir J*. 2000 Apr;15(4):670-5. Available at: <http://erj.ersjournals.com/content/15/4/670.long>. Accessed May 22, 2014.

Morgenthaler T, Alessi C, Friedman L, et al. Standards of Practice Committee, American Academy of Sleep Medicine. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. *Sleep*. 2007; 30(4):519-529. Available at: http://www.aasmnet.org/Resources/PracticeParameters/PP_Actigraphy_Update.pdf. Accessed May 21, 2014.

Mulgrew AT, Fox N, Ayas NT, et al. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. *Ann Intern Med*. 2007 Feb 6; 146 (3):157-66.

Pellegrino R., Viegi G., Brusasco V. et al. Series “ATS/ERS TASK FORCE: STANDARDISATION OF LUNGFUNCTION TESTING”, Interpretative strategies for lung function tests. *Eur Respir J* 2005; 26: 948–968.

Piper A, Grunstein R. Concise Clinical Review: Obesity Hypoventilation Syndrome, Mechanisms and Management. *J Respir Crit Care Med* Vol 183. pp 292–298, 2011. [www.http://ajrcm.atsjournals.org/content/183/3/292.full.pdf](http://ajrcm.atsjournals.org/content/183/3/292.full.pdf) Accessed May 22, 2014

Quan SF, Griswold ME, Iber C, et al. Sleep Heart Health Study (SHHS) Research Group. Short-term variability of respiration and sleep during unattended nonlaboratory polysomnography—the Sleep Heart Health Study. [corrected]. *Sleep*. 2002 Dec; 25(8):843-9. Erratum in: *Sleep*. 2009 Oct 1; 32(10): table of contents. Available at: <http://www.journalsleep.org/Articles/250802.pdf>. Accessed May 22, 2014.

Redline, S, Tosteson, T, Boucher, MA, et al. Measurement of sleep-related breathing disturbances in epidemiologic studies: assessment of the validity and reproducibility of a portable monitoring device. *Chest* 1991;100,1281-1286

Rinaldi V, Meyers AD. Medscape: Sleep-Disordered Breathing and CPAP Overview of Sleep-Disordered Breathing. Updated: December 17, 2013. Available at: <http://emedicine.medscape.com/article/870192-overview#showall>. Accessed May 22, 2014

Shatzmiller R, Passaro E. Insomnia. Medscape Reference; Drugs, Diseases and Procedures. Updated May 27, 2013. @: <http://emedicine.medscape.com/article/1187829> Accessed May 22, 2014

Skomro RP, Gjevre J, Reid J, et al. Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. *Chest*. 2010 Aug;138(2):257-63. Epub 2010 Feb 19.

Stepnowsky CJ Jr., Orr WC, Davidson TM. Nightly variability of sleep-disordered breathing measured over 3 nights. *Otolaryngol Head Neck Surg.* 2004 Dec; 131(6):837-43.

Trikalinos TA, Ip S, Roman G, et al. Home diagnosis of obstructive sleep apnea-hypopnea syndrome. *Technology assessment [Internet]* Rockville, MD: Agency for Healthcare Research and Quality 2007 Aug 8. Available at: <http://www.cms.gov/determinationprocess/downloads/id48TA.pdf>. Accessed May 22, 2014.

Wise M, Arand D, Auger R, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin, An American Academy of Sleep Medicine Report. *Sleep*, Vol. 30, No. 12, 2007.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
08/01/2014	<ul style="list-style-type: none"> • Changed policy title; previously titled <i>Polysomnography and Portable Monitoring for Sleep Related Breathing Disorders</i> • Revised benefit considerations; removed content/language specific to ASO plan membership • Reorganized/reformatted and revised coverage rationale: <ul style="list-style-type: none"> ○ Removed content/language specific to unattended full-channel or limited channel portable monitoring/home sleep test (HST) <p>Attended Full-Channel Nocturnal Polysomnography (NPSG)/Laboratory Sleep Test (LST)</p> <ul style="list-style-type: none"> ○ Combined guidelines for <i>patients previously diagnosed</i> and <i>patients not previously diagnosed</i> with obstructive sleep apnea (OSA); revised coverage statement to indicate attended full-channel nocturnal polysomnography (NPSG)/laboratory sleep test (LST), performed in a healthcare facility, is proven and medically necessary in patients with <i>suspected</i> OSA when the noted criteria is met ○ Revised list of proven/medically necessary indications: <p><i>Co-Morbid Conditions</i></p> <ul style="list-style-type: none"> ▪ Replaced reference to “co-morbid conditions” with “<i>documented co-morbid conditions</i>” ▪ Replaced reference to “neuromuscular disease/neurodegenerative disorder” with “<i>progressive neuromuscular disease/neurodegenerative disorder</i>” ▪ Replaced reference to “significant cardiac disease” with “<i>moderate to severe cardiac disease</i>” ▪ Replaced reference to “significant persistent cardiac arrhythmia” with “<i>uncontrolled cardiac tachyarrhythmia or bradyarrhythmia</i>” <p><i>Complex Sleep Disorders</i></p> <ul style="list-style-type: none"> ▪ Replaced reference to “sleep disorders” with “<i>complex sleep disorders</i>” ▪ Replaced “periodic limb movement disorder (PLMD)” with “<i>severe chronic periodic limb movement disorder (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing)</i>” ▪ Added “<i>restless leg syndrome (RLS)/Ekbom that has not responded to treatment</i>” <p><i>Age Requirement</i></p> <ul style="list-style-type: none"> ▪ Changed age requirement from “child or adolescent ≤ 20 years of age” to “child or adolescent < 18 years of age” <p>Actigraphy</p> <ul style="list-style-type: none"> ○ Added language to indicate actigraphy is unproven/not medically necessary for evaluation of circadian rhythm disorders; the evidence regarding use of actigraphy for evaluation of circadian rhythm disorders is

	<p>of low quality and therefore the clinical utility could not be established</p> <p>Split Night Study with Positive Airway Pressure (PAP) Titration</p> <ul style="list-style-type: none"> ○ Changed applicable site of service from “a healthcare facility” to “an attended sleep laboratory” <p>Full Night Study with Positive Airway Pressure (PAP) Titration</p> <ul style="list-style-type: none"> ○ Changed applicable site of service from “a healthcare facility” to “an attended sleep laboratory” ○ Revised criteria pertaining to the feasibility of a split night study; replaced criterion indicating the continuous positive airway pressure (CPAP) titration portion of the original study “failed to effectively eliminate respiratory events” with “failed to effectively <i>minimize</i> respiratory events” <p>Repeat Testing</p> <ul style="list-style-type: none"> ○ Changed applicable site of service from “a healthcare facility” to “an attended sleep laboratory” ● Revised definitions: <ul style="list-style-type: none"> ○ Added definition of: <ul style="list-style-type: none"> ▪ Obstructive Apnea ▪ Periodic Limb Movement (PLM) ▪ Periodic Limb Movement Arousal Index (PLMAI) ▪ Periodic Limb Movement Index (PLMI) ○ Updated definition of: <ul style="list-style-type: none"> ▪ Central Apnea ▪ Periodic Limb Movement Disorder (PLMD) ● Updated list of applicable ICD-9 diagnosis codes; removed 89.17 ● Updated list of applicable CPT codes; removed 95800, 95801 and 95806 ● Updated list of applicable HCPCS codes; removed G0398, G0399 and G0400 ● Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references ● Archived previous policy version 2014T0334P
--	--