

# ATTENDED POLYSOMNOGRAPHY FOR EVALUATION OF SLEEP DISORDERS

**Policy Number:** DIAGNOSTIC 023.28 T2

**Effective Date:** April 1, 2018

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Related Policies
<ul style="list-style-type: none"> <li>• <a href="#">Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements</a></li> <li>• <a href="#">Obstructive Sleep Apnea Treatment</a></li> </ul>

## INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

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.

## CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General benefits package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes <sup>1,3</sup>
Precertification with Medical Director Review Required	Yes <sup>1,2</sup>
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	All

## Special Considerations

<sup>1</sup>Precertification with review by a Medical Director or their designee is required for Attended/Laboratory Sleep Testing (LST), CPT codes 95782, 95783, 95805, 95807, 95808, 95810 and 95811. Precertification is not required for Unattended/Home Sleep Testing (HST); CPT codes 95800, 95801, 95806 and HCPCS codes G0398, G0399, G0400.

<sup>2</sup>Actigraphy as a stand-alone test (CPT code 95803) is not Medically Necessary and requires Medical Director review.

<sup>3</sup>Precertification is required for services covered under the Member's General Benefits package when performed in the office of a participating provider. For Commercial plans, precertification is not required, but is encouraged for out-of-network services performed in the office that are covered under the Member's General Benefits package. If precertification is not obtained, Oxford may review for Medical Necessity after the service is rendered.

## BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

### **Indications for Coverage**

- 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 (OSA). Refer to the applicable medical policy to determine if the treatment proposed is proven for OSA.
- Oral appliances for snoring with a diagnosis of OSA are addressed in the [Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements](#) policy.

### **Coverage Limitations and Exclusions**

- Medical treatment for primary snoring, without a diagnosis of OSA, that includes Positive Airway Pressure (PAP) equipment or oral appliances identified via a clinical review, is not a Covered Health Service.
- Surgical treatments for primary snoring, without a diagnosis of OSA, 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

### **Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

## COVERAGE RATIONALE

### **Home Sleep Apnea Testing (HSAT), using a portable monitor, is Medically Necessary for evaluating adults with suspected OSA.**

Where HSAT is indicated, an Autotitrating Positive Airway Pressure (APAP) device is an option to determine a fixed PAP pressure.

### **Attended full-channel nocturnal polysomnography, performed in a healthcare facility or laboratory setting, is Medically Necessary for evaluating individuals with suspected OSA when:**

- Results of previous HSAT are negative, indeterminate or technically inadequate to make a diagnosis of OSA; or

- Patient is a child or adolescent (i.e., less than 18 years of age); or
- Patient is known to have one or more of the following comorbid medical conditions that prohibits the use of a HSAT:
  - Significant [Chronic Pulmonary Disease](#) as defined by a forced expiratory volume (FEV<sub>1</sub>) % predicted of <60 (Pellegrino et al., 2005)
  - 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)
  - Moderate to severe heart failure (New York Heart Association class III or IV)
  - Body mass index (BMI) >50 (DeMaria et al., 2007; Blackstone and Cortés, 2010)
  - [Obesity Hypoventilation Syndrome](#)
  - Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder.

Also see [Attended Repeat Testing](#) section below.

**When a diagnosis of OSA has been excluded by appropriate clinical assessment or has been adequately treated, attended full-channel nocturnal polysomnography, performed in a healthcare facility or laboratory setting, is Medically Necessary for evaluating symptomatic individuals suspected of having one (1) or more of the following conditions:**

- [Periodic Limb Movement Disorder](#) (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing)
- [Restless Leg Syndrome \(RLS\)/Willis-Ekbom Disease](#) that has not responded to treatment
- [Parasomnia](#) with documented disruptive, violent or potentially injurious sleep behavior suspicious of Rapid Eye Movement Sleep Behavior Disorder ([RBD](#))
- [Narcolepsy](#), once other causes of Excessive Sleepiness have been ruled out by appropriate clinical assessment (also see [MSLT](#) section below)
- [Central Sleep Apnea](#)

**Attended full-channel nocturnal polysomnography, performed in a healthcare facility or laboratory setting is not Medically Necessary for diagnosing ANY of the following conditions:**

- [Circadian Rhythm Disorders](#)
- Depression
- [Insomnia](#)

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.

**Actigraphy is not Medically Necessary for diagnosing sleep disorders.**

A review of the evidence does not establish the effectiveness of Actigraphy as a stand-alone tool for the diagnosis of sleep disorders. In addition, definitive patient selection criteria for the use of Actigraphy devices for the diagnosis of sleep disorders have not been established.

### **Daytime Sleep Studies**

**Multiple Sleep Latency Testing (MSLT) is Medically Necessary for evaluating individuals with suspected Narcolepsy when other causes of Excessive Sleepiness have been excluded by appropriate clinical assessment.**

For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 22<sup>nd</sup> edition, 2018, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC).

**Maintenance of Wakefulness Testing (MWT) is Medically Necessary for evaluating individuals whose inability to remain awake constitutes a safety issue, or for assessing response to treatment in individuals with Narcolepsy or idiopathic Hypersomnia.**

For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 22<sup>nd</sup> edition, 2018, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC).

**Multiple Sleep Latency Testing (MSLT) and the Maintenance of Wakefulness Test (MWT) are not Medically Necessary for evaluating OSA, Insomnia or Circadian Rhythm disorders.**

Available published evidence is insufficient to demonstrate improved management of these conditions through the use of MSLT. Published evidence for OSA is limited to poorly controlled studies.

**An abbreviated daytime sleep study ([PAP-Nap](#)), to acclimate individuals to PAP and its delivery, is not Medically Necessary.**

Further results from large, prospective studies are needed to assess the clinical value of this test.

### **Attended PAP Titration**

**A split-night sleep study, performed in a healthcare facility or laboratory setting, is Medically Necessary for the diagnosis and PAP titration when an individual meets the above criteria for an attended sleep study.**

**When a split-night sleep study is inadequate or not feasible, a full-night study, performed in a healthcare facility or laboratory setting, is Medically Necessary for PAP titration when an individual meets the above criteria for an attended full-channel nocturnal polysomnography and has a confirmed diagnosis of OSA.** (Also see [Attended Repeat Testing](#) section below).

### **Attended Repeat Testing**

Repeat attended full-channel nocturnal polysomnography, performed in a health care facility or laboratory setting, as well as repeat PAP titration, is Medically Necessary for certain individuals who have persistent or new symptoms, despite documented appropriate current treatment or PAP therapy (e.g., equipment failure, improper mask fit, pressure leaks, inadequate pressure and medical problems including nasal congestion have been addressed and appropriately managed).

Repeat testing and repositioning/adjustments for oral sleep appliances can be done in the home unless the patient meets [criteria](#) for an attended sleep study.

## **DEFINITIONS**

**Actigraphy:** A measurement of physical activity, typically via a wrist-worn movement sensor, employed to estimate sleep and wakefulness based on relative levels of physical inactivity and activity. (ICSD-3, 2014)

**Apnea:** The cessation of airflow ( $\geq 90\%$  decrease in airflow compared to baseline) lasting at least 10 seconds. Apneas are classified as obstructive, central or mixed based on the pattern of respiratory effort. An obstructive Apnea is associated with continued or increased inspiratory effort throughout the entire period of absent airflow. A Central Apnea is associated with absent inspiratory effort throughout the entire period of absent airflow. Mixed Apneas are associated with absent inspiratory effort in the initial portion of the event, followed by resumption of inspiratory effort in the second portion of the event. (AASM Scoring Manual, 2017)

**Apnea Hypopnea Index (AHI):** The number of Apneas plus the number of Hypopneas, times 60, divided by total sleep time. (AASM Scoring Manual, 2017)

**Central Disorders of Hypersomnolence:** Sleep disorders in which the primary complaint is daytime sleepiness not caused by disturbed nocturnal sleep or misaligned Circadian Rhythms. (ICSD-3, 2014)

**Central Sleep Apnea (CSA):** A condition in which a person stops breathing during sleep because the brain temporarily stops sending signals to the muscles that control breathing. (Eckert et al., 2007)

**Chronic Pulmonary Disease (CPD):** A method of categorizing the severity of lung function impairment based on forced expiratory volume (FEV<sub>1</sub>) % predicted is provided in the below table. Severity of any spirometric abnormality based on the forced expiratory volume in one second (FEV<sub>1</sub>).

Degree of Severity	FEV1 % Predicted
Mild	>70
Moderate	60-69
Moderately severe	50-59
Severe	35-49
Very Severe	<35

*(Pellegrino et al., 2005)*

**Circadian Rhythm:** Circadian Rhythms are near-24-hour biological rhythms that exist in all living organisms. The internal circadian clock is synchronized to the 24-hour light-dark cycle. (ICDS-3, 2014)

**Circadian Rhythm Sleep-Wake Disorders:** Sleep disorders caused by alterations of the Circadian time-keeping system, its entrainment mechanisms or a misalignment of the endogenous Circadian Rhythm and the external environment. (ICDS-3, 2014)

**Epworth Sleepiness Scale (ESS):** The ESS is an 8-item questionnaire which is used to determine the level of a person's daytime sleepiness. The ESS is based on the patient's assessment of the likelihood of falling asleep in certain situations commonly encountered in daily life. See the following website for further information: <http://epworthsleepinessscale.com/about-the-ess/>. (Accessed September 18, 2017)

**Excessive Sleepiness [Somnolence, Hypersomnia, Excessive Daytime Sleepiness (EDS)]:** Sleepiness that occurs in a situation when an individual would usually be expected to be awake and alert. (Littner et al., 2005)

**Home Sleep Apnea Testing:** The use of unattended diagnostic studies to assess for OSA without the determination of sleep stage. The term specifies the condition being assessed (i.e., Sleep Apnea) by current technology without implying that "sleep" quality, staging or time are determined. Not all such studies are performed at home; however, that is where the vast majority of patients undergo these tests. (AASM Style Guide, 2015) Also referred to as out-of-center sleep testing or portable monitoring.

**Hypersomnia (Excessive Sleepiness):** A disorder characterized by Excessive Sleepiness (e.g., idiopathic hypersomnia). (ICSD-3, 2014)

**Hypersomnolence:** Excessive Sleepiness during the normal wake period. (ICSD-3, 2014)

**Hypopnea:** An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or the event is associated with an arousal. (AASM Scoring Manual, 2017)

**Insomnia:** A persistent difficulty with sleep initiation, duration, consolidation or quality that occurs despite adequate opportunity and circumstances for sleep, and results in some form of daytime impairment. (ICSD-3, 2014)

**Maintenance of Wakefulness Test (MWT):** A daytime sleep study that measures the ability to stay awake for a defined period of time. (Littner et al., 2005)

**Medically Necessary:** Health care services provided for the purpose of preventing, evaluating, diagnosing or treating a sickness, injury, mental illness, substance use disorder, 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 a sickness, injury, mental illness, substance use disorder, disease or its symptoms
- Not mainly for the convenience of the member or that of the 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 a 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 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. (UnitedHealthcare 2011 Certificate of Coverage)

**Monitoring Time:** Total recording time minus periods of artifact and time the patient was awake as determined by Actigraphy, body position sensor, respiratory pattern or patient diary. (AASM Scoring Manual, 2017)

**Multiple Sleep Latency Test (MSLT):** A daytime sleep study that measures physiological sleep tendency under standardized conditions in the absence of external alerting factors. (Littner et al., 2005)

**Narcolepsy:** A condition in which a person experiences Excessive Daytime Sleepiness and may fall asleep at unexpected times, such as during work, school or driving. Narcolepsy type 1 is characterized by Excessive Daytime Sleepiness, Cataplexy and/or low or absent cerebrospinal fluid hypocretin-1 levels. (ICSD-3, 2014) Narcolepsy type 2 is characterized by Excessive Daytime Sleepiness, without Cataplexy, with unmeasured or normal cerebrospinal fluid hypocretin-1 levels. (ICSD-3, 2014)

**Obesity Hypoventilation Syndrome (OHS):** A breathing disorder characterized by obesity (BMI > 30 kg/m<sup>2</sup>) and daytime hypercapnia (arterial PaCO<sub>2</sub> > 45 mm Hg) that cannot be fully attributed to an underlying cardiopulmonary or neurologic disease. The condition leads to low oxygen levels and too much carbon dioxide in the blood. (ICSD-3, 2014)

**Obstructive Sleep Apnea (OSA):** A condition in which a person stops breathing during sleep due to a narrowed or closed airway.

**PAP-Nap:** PAP-Nap is a daytime, abbreviated cardio-respiratory sleep study for patients who experience anxiety about starting PAP therapy or are having problems tolerating PAP therapy. The test combines psychological and physiological treatments into one procedure and includes mask and pressure desensitization, emotion-focused therapy to overcome aversive emotional reactions, mental imagery to divert patient attention from mask or pressure sensations and physiological exposure to PAP therapy during a 100-minute nap period. (Krakow et al., 2008)

**Parasomnia:** Parasomnias are undesirable physical events or experiences that occur during entry into sleep, within sleep or during arousal from sleep. They may occur during non-Rapid Eye Movement sleep, Rapid Eye Movement sleep (REM) or during transitions to and from sleep. Parasomnias encompass abnormal sleep related complex movements, behaviors, emotions, perceptions, dreams and autonomic nervous system activity. They are clinical disorders because of the resulting injuries, sleep disruption, adverse health effects and untoward psychosocial effects. (ICSD-3, 2014) Also, see [RBD](#).

**Periodic Limb Movement Arousal Index (PLMAI):** The number of PLMS associated with an arousal, times 60, divided by total sleep time. (AASM Scoring Manual, 2017)

**Periodic Limb Movement Disorder (PLMD):** A sleep disorder characterized by periodic episodes of repetitive highly stereotyped limb movements that occur during sleep, in conjunction with clinical sleep disturbance or fatigue that cannot be accounted for by another primary sleep disorder or other etiology. (ICSD-3, 2014)

**Periodic Limb Movement Index (PLMI):** The number of PLMS, times 60, divided by total sleep time. (AASM Scoring Manual, 2017)

**Periodic Limb Movement of Sleep (PLMS):** Movements of the limbs during sleep occurring with a specified frequency, duration and amplitude. (AASM Scoring Manual, 2017)

**Polysomnogram:** A laboratory-based sleep study that uses multiple channels to record a wide range of physiological information, including brain activity, eye movements, body movements, breathing and heart rate. (American Thoracic Society, 2015)

**Positive Airway Pressure (PAP):** A PAP device is an air pump (fan-driven or turbine system) that draws in external, filtered air and delivers pressurized airflow to keep an individual's airway open. PAP devices are divided into four basic types depending on their pressure delivery system:

- Continuous Positive Airway Pressure (CPAP) – delivers a steady, fixed flow of air pressure on inhalation
- Bilevel Positive Airway Pressure (BPAP) - delivers a higher flow of air pressure on inhalation than exhalation
- Autotitrating Positive Airway Pressure (APAP) – automatically changes the flow of air pressure (CPAP or BPAP) based on an individual's breathing patterns
- Adaptive Servoventilation (ASV) - uses a servocontroller to automatically adjust the flow of air pressure by breath-by-breath analysis to maintain a steady minute ventilation. (Kushida et al., 2008)

**Rapid Eye Movement Sleep Behavior Disorder (RBD):** A Parasomnia characterized by abnormal behaviors emerging during REM sleep that may cause injury or sleep disruption. (ICSD-3, 2014)

**Respiratory Disturbance Index (RDI):** The number of Apneas plus the number of Hypopneas plus the number of respiratory effort-related arousals, times 60, divided by total sleep time. (AASM Scoring Manual, 2017)

**Respiratory Effort-Related Arousal (RERA):** A sequence of breaths characterized by increasing respiratory effort, inspiratory flattening in the nasal pressure or PAP device flow channel or an increase in end-tidal PCO<sub>2</sub> (children) leading to an arousal from sleep. Respiratory Effort-Related Arousals do not meet criteria for Hypopnea and have a minimum duration of at least 10 seconds in adults or the duration of at least two breaths in children. (AASM Scoring Manual, 2017)

**Respiratory Event Index (REI):** Total number of respiratory events scored, times 60, divided by Monitoring Time. The REI is used for HSAT and is a surrogate for AHI. (AASM Scoring Manual, 2017)

**Restless Legs Syndrome (RLS)/Willis-Ekbom Disease:** RLS is a sensorimotor disorder characterized by a complaint of a strong, irresistible urge to move the limbs. This urge to move is often, but not always, accompanied by other uncomfortable sensations felt deep inside the limbs or by a feeling that is difficult or impossible to describe. Although the legs are most prominently affected, these sensations may occur in the arms as well. (ICSD-3, 2014)

## APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CPT Code	Description
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of Continuous Positive Airway Pressure therapy or bi-level ventilation, attended by a technologist
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
95805	Multiple Sleep Latency or Maintenance Of Wakefulness Testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; 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 a technologist

*CPT® is a registered trademark of the American Medical Association*

HCPCS Code	Description
G0398	Home Sleep Study Test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
G0399	Home Sleep Test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400	Home Sleep Test (HST) with type IV portable monitor, unattended; minimum of 3 channels

## DESCRIPTION OF SERVICES

Sleep disorders are conditions that affect an individual's normal sleep patterns and can have an impact on quality of life. One of the most common sleep disorders is Obstructive Sleep Apnea (OSA), a condition in which a person stops breathing during sleep due to a narrowed or closed airway. Symptoms of OSA include daytime sleepiness, loud snoring and breathing interruptions or awakenings due to gasping or choking. If left untreated, OSA can lead to serious health consequences such as hypertension, heart disease, stroke, insulin resistance and obesity. Other sleep disorders include Central Sleep Apnea, Periodic Limb Movement Disorder (PLMD), Narcolepsy, Restless Legs Syndrome, Parasomnias and Insomnia.

The evaluation of sleep disorders can be done at home or in a specialized sleep center that can study sleep patterns during the day or at night. Home Sleep Apnea Testing (HSAT) is used to diagnose OSA and records breathing rate, airflow, heart rate and blood oxygen levels during sleep. These studies are performed at home without a sleep technician present (unattended). Polysomnography (PSG) records breathing, heart rate, blood oxygen levels, body movements, brain activity and eye movements during sleep. PSG is performed in a laboratory setting with a sleep technician present (attended). (American Thoracic Society, 2015)

Once a diagnosis of OSA is made, a PAP trial (titration) is performed to determine the optimal amount of pressure needed to prevent the airway from narrowing or closing. An attended split-night study combines diagnostic polysomnography and PAP titration into a single night. (American Thoracic Society, 2015)

Sleep studies conducted during the day include the Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT). MSLT is performed to measure daytime sleepiness and is most often used to diagnose Narcolepsy. MWT is performed to measure how well a person can stay awake. In addition to diagnosing sleep disorders, PSG may also be used to assess and adjust the treatment plan. (American Thoracic Society, 2015)

### **Additional Information**

According to the American Academy of Sleep Medicine (AASM) (Epstein et al., 2009) the diagnosis of OSA is confirmed if the number of obstructive events\* (Apneas, Hypopneas + Respiratory Event Related Arousals) on 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 AHI or 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  $\geq 5$  and  $< 15$
- Moderate for AHI or RDI  $\geq 15$  and  $\leq 30$
- 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 PSG ( $\geq 7$  channels) in a laboratory setting
- Type 2: full unattended PSG ( $\geq 7$  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](http://www.aasmnet.org/Resources/PracticeParameters/Outofcenter.pdf). (Accessed September 20, 2017)

### **Multiple-Night Home Sleep Apnea Testing versus One-Night Home Sleep Apnea Testing**

Results of clinical studies demonstrate that night-to night variability in HSAT is comparable to laboratory-based PSG. The reported RDI variability is small and a single night testing can correctly diagnose 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 HSAT in the high-risk patient is normal or technically inadequate the AASM recommends in-laboratory PSG. (Collop et al., 2007)

## **CLINICAL EVIDENCE**

In 2011, AHRQ published a comparative effectiveness review on the diagnosis and treatment of OSA 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 ESS are independent predictors of CPAP compliance.
- There is low evidence that some treatments improve CPAP compliance.

The report concluded that portable monitors and questionnaires may be effective screening tools, but assessments with clinical outcomes are necessary to prove their value over PSG. 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.

Flemons et al. (2003) did a comprehensive review of the published literature on portable monitors for PSG. The review was cosponsored by the AASM, the American College of Chest Physicians (ACCP), and the American Thoracic Society (ATS). The authors 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 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/Bedbugg/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 CO<sub>2</sub> (ETCO<sub>2</sub>), 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>. (Accessed September 20, 2017)

### **Single-Night versus Multiple-Night Home Sleep Apnea Testing**

A single-night PSG 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 (ARES™) 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 PSG AHI and AI values. Both the overall PSG 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 HSAT 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 nights. 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 HSAT is comparable to laboratory-based PSG 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 CPAP treatment, compared to patients managed with in laboratory PSG. (Kuna, 2010)

Mulgrew et al. (2007) randomly assigned 68 high-risk patients identified by a diagnostic algorithm to 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 by McArdle et al. (2010). 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. The mean nightly adherence, decrease in ESS 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  $1.74 \pm 2.81$  in the home group and  $1.85 \pm 2.46$  in the in-laboratory group. CPAP adherence was  $3.5 \pm 2.5$  hours/day in the home group and  $2.9 \pm 2.3$  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 CPAP 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, ESS score, OSLER, Functional Outcomes of Sleep Questionnaire, or SF-36 between the groups. (Cross et al., 2006)

In a randomized, single-blinded crossover trial Bakker et al. (2011) compared the effectiveness of CPAP and APAP (S8 Autoset II<sup>®</sup>, 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  $75.8 \pm 32.7$ , body mass index  $49.9 \pm 5.2$  kg m<sup>-2</sup>, mean pressure 16.4 cmH<sub>2</sub>O) without significant co-morbid disease. Both therapies substantially reduced the AHI (APAP  $9.8 \pm 9.5$  and CPAP  $7.3 \pm 6.6$  events h<sup>-1</sup>;  $P=0.35$ ), 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 ( $14.2 \pm 2.7$  and  $16.1 \pm 1.8$  cmH<sub>2</sub>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 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 CPAP 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 PSG does not adversely affect short-term CPAP adherence in patients with OSA.

Gao et al. (2012) 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 ESS (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**

Current evidence evaluating actigraphy for the diagnosis of sleep disorders is very limited and does not establish the effectiveness of actigraphy as a stand-alone diagnostic tool.

Plante (2014) conducted a systematic review and meta-analysis on the use of leg actigraphy for diagnosing periodic limb movements of sleep (PLMS). Findings demonstrated significant heterogeneity among a limited number of studies in terms of type of actigraph utilized, position of the device on the lower extremity and methods employed to count PLMS. In general, common accelerometers vary in their sensitivity and specificity to detect PLMS, which is likely related to the technical specifications of a given device. A current limitation in the ability to combine data from actigraphs placed on both legs is also a significant barrier to their use in clinical settings. Further research is required to determine the optimal methods to quantify PLMS using leg actigraphy, as well as specific clinical situations in which these devices may prove most useful.

### **PAP-Nap Test**

In a pilot study, Krakow et al. (2008) assessed the impact of the PAP-Nap sleep study on adherence to PAP therapy among Insomnia patients with sleep disordered breathing (SDB). The PAP-Nap test combines psychological and physiological treatments into one procedure and includes mask and pressure desensitization, emotion-focused therapy to overcome aversive emotional reactions, mental imagery to divert patient attention from mask or pressure sensations and physiological exposure to PAP therapy during a 100-minute nap period. Patients treated with the PAP-Nap test (n=39) were compared to a historical control group (n = 60) of Insomnia patients with SDB who did not receive the test. All 99 Insomnia patients were diagnosed with SDB (mean AHI 26.5 +/- 26.3, mean RDI 49.0 +/- 24.9), and all reported a history of psychiatric disorders or symptoms as well as resistance to PAP therapy. Among 39 patients completing the PAP-Nap, 90% completed overnight titrations, compared with 63% in the historical control group. Eight-five percent of the nap-tested group filled PAP therapy prescriptions for home use compared with 35% of controls. Sixty-seven percent of the nap-tested group maintained regular use of PAP therapy compared with 23% of the control group. Using standards from the field of sleep medicine, the nap-tested group demonstrated objective adherence of 49% to 56% compared to 12% to 17% among controls. Further results from large, prospective studies are needed to assess the clinical value of this test.

### **Professional Societies**

#### ***American Academy of Sleep Medicine (AASM)***

Updated clinical practice guidelines (Kapur et al., 2017) describe the circumstances under which attended PSG in an accredited sleep center or HSAT should be performed for suspected OSA in adults. In these guidelines, which consisted of a systematic review of the evidence, AASM made the following recommendations:

#### **Good Practice Statements:**

- Diagnostic testing for OSA should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up.
- PSG is the standard diagnostic test for the diagnosis of OSA in adult patients in whom there is a concern for OSA based on a comprehensive sleep evaluation.

#### **Recommendations:**

- AASM recommends that clinical tools, questionnaires and prediction algorithms not be used to diagnose OSA in adults, in the absence of PSG or HSAT. (STRONG)
- AASM recommends that PSG, or HSAT with a technically adequate device, be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA. (STRONG)
- AASM recommends that if a single HSAT is negative, inconclusive, or technically inadequate, PSG be performed for the diagnosis of OSA. (STRONG)
- AASM recommends that PSG, rather than HSAT, be used for the diagnosis of OSA in patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake

hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia. (STRONG)

- AASM suggests that, if clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for PSG be used for the diagnosis of OSA. (WEAK)
- AASM suggests that when the initial PSG is negative and clinical suspicion for OSA remains, a second PSG be considered for the diagnosis of OSA. (WEAK)

Per AASM, a strong recommendation is one that clinicians should follow under most circumstances. A weak recommendation reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients. The ultimate judgment regarding propriety of any specific care must be made by the clinician in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options and resources.

The 2009 updated AASM clinical guideline for the evaluation, management and long-term care of OSA 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, et.al. 2009)

A practice parameter by Littner et al. (2005), regarding the clinical use of the MSLT and the MWT concluded the following:

- The MSLT is indicated as part of the evaluation of patients with suspected Narcolepsy to confirm the diagnosis.
- The MSLT may be indicated as part of the evaluation of patients with suspected idiopathic hypersomnia to help differentiate idiopathic hypersomnia from narcolepsy.
- 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 CPAP.
- The MSLT is not routinely indicated for evaluation of sleepiness in medical and neurological disorders (other than narcolepsy), insomnia, or circadian rhythm disorders.
- Repeat MSLT testing may be indicated in the following situations:
  - When the initial test is affected by extraneous circumstances or when appropriate study conditions were not present during initial testing
  - When ambiguous or uninterpretable findings are present
  - When the patient is suspected to have narcolepsy but earlier MSLT evaluation(s) did not provide polygraphic confirmation
- The MWT may be indicated in patients with excessive sleepiness to assess response to treatment.
- The MWT may be used to assess an individual's ability to remain awake when his or her inability to remain awake constitutes a public or personal safety issue.

## U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Systems to record and analyze PSG information are regulated by the FDA as Class II Devices under the 510(k) premarketing notification process. See the following website for more information (use product code GWQ): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed September 18, 2017)

The FDA has approved several HSAT devices as ventilatory effort recorders under the 510(k) premarketing notification process. See the following website for more information (use product code MNR): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed September 18, 2017)

Actigraphy devices are classified as electroencephalograph devices (product code GWQ) or ventilatory effort recorders (product code MNR). See the following website for more information: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed September 18, 2017)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
04/01/2018	<ul style="list-style-type: none"><li>• Revised coverage rationale; replaced references to "MCG™ Care Guidelines, 21<sup>st</sup> edition, 2017" with "MCG™ Care Guidelines, 22<sup>nd</sup> edition, 2018"</li><li>• Archived previous policy version DIAGNOSTIC 023.27 T2</li></ul>