ATTENDED POLYSOMNOGRAPHY FOR EVALUATION OF SLEEP DISORDERS

Protocol: PUL004
Effective Date: June 1, 2017

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INSTRUCTIONS FOR USE

This protocol 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 Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

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

Before using this guideline, please check the enrollee specific 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 protocol to determine if the treatment proposed is **medically necessary** 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 Protocol.

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

COMMERCIAL 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 auto-titrating continuous 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:
  o Significant chronic pulmonary disease as defined by a forced expiratory volume (FEV₁) % predicted of <60 (Pellegrino et al., 2005)
  o 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)
  o Moderate to severe heart failure (New York Heart Association class III or IV)
  o Body mass index (BMI) >50 (DeMaria et al., 2007, Blackstone and Cortés, 2010)
  o Obesity hypoventilation syndrome
  o Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder.

• Also see Repeat Testing section below.

When a diagnosis of OSA has been excluded or 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:
• Severe chronic periodic limb movement disorder (PLMD) (not leg movements associated with another disorder such as sleep disordered breathing)
• Restless legs 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 (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 evaluating sleep-related breathing and circadian rhythm disorders.

A review of the evidence does not establish the effectiveness of actigraphy as a stand-alone tool for the diagnosis of OSA. In addition, definitive patient selection criteria for the use of actigraphy devices for the diagnosis of sleep apnea have not been established. The evidence regarding the use of actigraphy for the evaluation of circadian rhythm disorders is of low quality; therefore, the clinical utility cannot be 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.

For information regarding medical necessity review, when applicable, see MCG™ Care Guidelines, 21st edition, 2017, 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, 21st edition, 2017, Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT), A-0146 (AC).

**MCG™ Guidelines 21st edition A-0146**

**Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT)**

**Clinical indications for procedure**

• MSLT or MWT may be indicated for 1 or more of the following:
MSLT assessment of suspected narcolepsy and other disorders of excessive daytime sleepiness, as indicated by 1 or more of the following:

- Initial test needed, as indicated by 1 or more of the following:
  - Cataplexy (i.e., sudden weakness or loss of muscle tone not accompanied by loss of consciousness)
  - Disturbed or fragmented sleep
  - Excessive daytime sleepiness
  - Hallucinations with sleep onset (hypnagogic) or upon awakening (hypnopompic)
  - Sleep paralysis

- Repeat test needed, as indicated by 1 or more of the following:
  - Initial MSLT results indeterminate
  - Initial MSLT results negative, but strong clinical suspicion of narcolepsy

MWT assessment of sleep disorders, as indicated by 1 or more of the following:

- Assessment of patient for whom inability to remain awake constitutes safety issue (e.g., patient is airplane pilot)
- Assessment of patient with narcolepsy or idiopathic hypersomnia to assess response to treatment

**Inconclusive or Non-Supportive Evidence**

For obstructive sleep apnea, evidence demonstrates a lack of net benefit; additional research is recommended. The MSLT is not routinely indicated for initial evaluation and diagnosis of obstructive sleep apnea or for assessment of treatment with continuous positive airway pressure.

*** End of MCG Guidance ***

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 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 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 Repeat Testing section below.
Attended Repeat Testing
It may be necessary to perform repeat sleep studies. Where repeat testing is indicated, attended full-channel nocturnal polysomnography, performed in a healthcare facility or laboratory setting, is medically necessary for individuals who meet the above criteria for an attended sleep study. 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 inactivity (ICSD-3, 2014).

Apnea: The cessation of airflow (≥90% decrease in airflow compared to baseline) lasting at least 10 seconds. Apneas are classified as obstructive, mixed, or central 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, 2016).

Apnea Hypopnea Index (AHI): The number of apneas plus the number of hypopneas, times 60, divided by total sleep time (AASM Scoring Manual, 2016).

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 (FEV₁) % pred is provided in the below table. Severity of any spirometric abnormality based on the forced expiratory volume in one second (FEV₁).

<table>
<thead>
<tr>
<th>Degree of Severity</th>
<th>FEV₁ % pred</th>
</tr>
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<tbody>
<tr>
<td>Mild</td>
<td>&gt;70</td>
</tr>
<tr>
<td>Moderate</td>
<td>60-69</td>
</tr>
<tr>
<td>Moderately severe</td>
<td>50-59</td>
</tr>
<tr>
<td>Severe</td>
<td>35-49</td>
</tr>
<tr>
<td>Very Severe</td>
<td>&lt;35</td>
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</table>

(Pellegrino et al., 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).
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/](http://epworthsleepinessscale.com/about-the-ess/) Accessed April 2017.

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 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).

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): 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). The term excessive sleepiness is preferred to describe the symptom (AASM, 2001).

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 4% decrease in oxygen saturation as compared to baseline (AASM Scoring Manual, 2016).

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 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).

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. Monitoring time is used to calculate the respiratory event index for home sleep apnea testing (AASM Scoring Manual, 2016).
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).

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/m2) and daytime hypercapnia (arterial PaCO2 > 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, 2016).

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. PLMS occur most frequently in the lower extremities. They typically involve extension of the big toe, often in combination with partial flexion of the ankle, the knee and sometimes, the hip. Similar movements can occur in the upper limbs (ICSD-3, 2014).
<table>
<thead>
<tr>
<th>Degree of Severity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Associated with a PLMI of 5-24 per hour and results in mild insomnia or mild sleepiness</td>
</tr>
<tr>
<td>Moderate</td>
<td>Associated with a PLMI of 25-49 per hour and results in moderate insomnia or sleepiness</td>
</tr>
<tr>
<td>Severe</td>
<td>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</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Type</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>1 month or less</td>
</tr>
<tr>
<td>Subacute</td>
<td>Greater than 1 month but less than 6 months</td>
</tr>
<tr>
<td>Chronic</td>
<td>6 months</td>
</tr>
</tbody>
</table>

(Hening et al., 1999)

**Periodic Limb Movement Index (PLMI):** The number of PLMs, times 60, divided by total sleep time (AASM Scoring Manual, 2016).

**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).

**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, 2016).

**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 PCO2 (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, 2016).

**Respiratory Event Index (REI):** Total number of respiratory events scored, times 60, divided by monitoring time. The REI is used for home sleep apnea testing (AASM Scoring Manual, 2016).

**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).

**MEDICARE COVERAGE RATIONALE**

Medicare covers polysomnography testing when criteria are met. Refer to the National Coverage Determinations (NCD) for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1). Nevada does have a Local Coverage Determination (LCD) for Polysomnography and Sleep Studies for Testing Sleep and April 2017).

**Sleep Testing for Obstructive Sleep Apnea (OSA) (NCD 240.4.1)**

**Item/Service Description**

Obstructive sleep apnea (OSA) is the collapse of the oropharyngeal walls and the obstruction of airflow occurring during sleep. Diagnostic tests for OSA have historically been classified into four types. The most comprehensive is designated Type I attended facility based polysomnography (PSG), which is considered the reference standard for diagnosing OSA. Attended facility based polysomnogram is a comprehensive diagnostic sleep test including at least electroencephalography (EEG), electro-oculography (EOG), electromyography (EMG), heart rate or electrocardiography (ECG), airflow, breathing/respiratory effort, and arterial oxygen saturation (SaO2) furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed. Overnight PSG is the conventional diagnostic test for OSA. The American Thoracic Society and the American Academy of Sleep Medicine have recommended supervised PSG in the sleep laboratory over 2 nights for the diagnosis of OSA and the initiation of continuous positive airway pressure (CPAP).

Three categories of portable monitors (used both in attended and unattended settings) have been developed for the diagnosis of OSA. Type II monitors have a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, breathing/respiratory effort, SaO2)-this type of device monitors sleep staging, so AHI can be calculated). Type III monitors have a minimum of 4 monitored channels including ventilation or airflow (at least two channels of respiratory movement or respiratory movement and airflow), heart rate or ECG, and oxygen saturation. Type IV devices may measure one, two, three or more parameters but do not meet all the criteria of a higher category device. Some monitors use an actigraphy algorithm to identify periods of sleep and wakefulness.
Indications and Limitations of Coverage

Nationally Covered Indications

Effective for claims with dates of service on and after March 3, 2009, the Centers for Medicare & Medicaid Services finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary’s treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.

2. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

3. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

4. Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

Nationally Non-Covered Indications

Effective for claims with dates of services on and after March 3, 2009, other diagnostic sleep tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP and are not covered.

Polysomnography and Sleep Studies for Testing Sleep and Respiratory Disorders

LCD (L34216)

Coverage Indications, Limitations, and/or Medical Necessity

Polysomnography is the continuous measurement and recording of physiological activities during sleep. During polysomnography, several parameters are recorded to establish a diagnosis or rule out sleep apnea, narcolepsy and other sleep disorders. The studies are also performed to evaluate a patient's response to therapy, such as CPAP (continuous positive airway pressure).

The coverage of impotence, which may involve sleep testing, is not addressed in this LCD.

Polysomnography is the continuous, simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for 6 hours or more, and includes a physician review, interpretation and report. Testing is covered when performed by an Independent Diagnostic Testing Facility for Sleep Disorders, a sleep laboratory or hospital. These are facilities in which certain conditions are diagnosed through the study of sleep and must be under the supervision of a physician.
These entities are for diagnosis, therapy, and research and may be affiliated with a hospital or be a freestanding facility. Some diagnostic or therapeutic services that are provided by these facilities may be covered under Medicare. Whether the facility is affiliated with a hospital or is freestanding and under the direction and control of physicians, coverage for diagnostic services under some circumstances is allowed under provisions of the law that are different from those for coverage of therapeutic services.

Diagnostic testing that is routinely performed by Independent Diagnostic Testing Facilities for Sleep Disorders may be covered even in the absence of direct supervision by a physician, however, a trained, qualified attendant must be present to assess and monitor the patient. Patients are referred to the Independent Diagnostic Testing Facilities for Sleep Disorders by their attending physician. These testing facilities are expected to maintain a record of the attending physician's orders. The need for diagnostic testing is confirmed by medical evidence, for example, physician examinations and laboratory tests. Diagnostic testing that is duplicative of previous testing done by the attending physician to the extent the results are still pertinent is not covered because it is not reasonable and necessary.

**Continuous Positive Airway Pressure (CPAP) Device**

Durable Medical Equipment

A. General

Continuous positive airway pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

The use of CPAP is covered under Medicare when used in adult patients with moderate or severe OSA for whom surgery is a likely alternative to CPAP. The use of CPAP devices must be ordered and prescribed by the licensed treating physician to be used in adult patients with moderate to severe OSA if either of the following criterion using the Apnea-Hypopnea Index (AHI) or Respiratory Distress Index (RDI) is met:

- AHI or RDI greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

The AHI is equal to the average number of episodes of apnea and hypopnea per hour. The Respiratory Disturbance Index (RDI) is equal to the average respiratory disturbances per hour. Both should be based on a minimum of 2 hours of sleep recorded, if the AHI or RDI is calculated on less than two hours of continuously recorded sleep, the total number of recorded events to calculate the AHI or RDA during sleep testing must be at a minimum the number of events that would have been required in a two hour period.

These tests are recorded by polysomnography or by sleep testing devices that are unattended in or out of a sleep lab facility or attended in a sleep lab facility using a FDA approved Type II, III, or IV portable device recording at least 3 channels using actual recorded hours of sleep.
Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent oxygen desaturation.

The polysomnography must be performed in a facility-based sleep study laboratory, and not in the home or in a mobile facility.

Performance of home sleep testing is limited to FDA cleared devices furnished with adequate patient instruction and support to assure successful completion of the studies. Provision of the device, patient instruction and support can be provided by accredited sleep centers as well as Independent Diagnostic Testing Facilities and other entities that can demonstrate use of FDA approved devices, inspection of the devices, and the patient support activities required. The provider may be subject to post payment audit to document these activities.

Physician services related to home sleep testing are covered for the purpose of determining a diagnosis of OSA if:
- It is reasonable and necessary for the diagnosis of the patient’s condition
- It is performed for patients with a high pretest probability of moderate to severe OSA
- It is performed in conjunction with a comprehensive sleep evaluation
- It meets all other Medicare requirements

The DMAC (Durable Medical Equipment Administrative Contractors) are responsible for providing coverage guidance on CPAP devices. The DMACS have published a policy that requires the standards of credentialing for individuals who interpret the sleep testing results that are required for coverage of CPAP.

"For all PAP devices, the sleep test (Type 1 - IV, Other) must be interpreted by a physician who holds either:
- Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or
- Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or
- Completed residency or fellowship training by" a program approved by "an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or
- Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC) or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations - JCAHO).

Nationally Non-covered Indications
“Polysomnography is distinguished from sleep studies by the inclusion of sleep staging which is defined to include a 1-4 lead electroencephalogram (EEG), an electrooculogram EOG), and a submental electromyogram (EMG). Additional parameters of sleep include:

1. ECG (electrocardiogram)
2. airflow
3. ventilation and respiratory effort
4. gas exchange by oximetry, transcutaneous monitoring, or end tidal gas analysis
5. extremity muscle activity, motor activity-movement
6. extended EEG monitoring
7. penile tumescence
8. gastroesophageal reflux
9. continuous blood pressure monitoring
10. snoring
11. body positions, etc.

For a study to be reported as a polysomnogram, sleep must be recorded and staged.” (CPT 2005)

The Multiple Sleep Latency Test (MSLT) is a standardized and well-validated measure of physiologic sleepiness. The same parameters as for basic Polysomnography (PSG) are monitored, (usually two eye movements and two EEG [central and occipital] channels, in addition to EKG, airflow, and submental EMG). The MSLT consists of 4-5 twenty-minute nap opportunities offered at two-hour intervals. The MSLT is designed to quantitate sleepiness to determine the need for treatment, and to determine the premature occurrence of REM (rapid eye movement) sleep. Studies in normals have demonstrated that the latency to sleep onset during these naps is correlated with the duration of sleep on one or several nights preceding the study, maturation, age, continuity of sleep, time of day, and ingestion of drugs. Pathologic ranges of sleep latency have been carefully defined. To insure validity, proper interpretation of the MSLT can only be made following a PSG that was performed on the preceding night. For each nap, the latency between "lights out" and sleep onset is determined. A mean latency of 5 minutes or less indicates severe excessive sleepiness. The number of naps during which REM sleep appears is also noted. Repeat MSLT testing is necessary only when 1) the initial test is believed to be an invalid representation of the patient's status; 2) the initial test is inconclusive; 3) the response to treatment needs to be ascertained; or 4) more than one sleep disorder is suspected.

Polysomnography and/or Multiple Sleep Latency studies are done and covered only if the patient has symptoms or complaints suggesting a diagnosis of one of the following conditions:

A. Narcolepsy
This term refers to a syndrome that is characterized by abnormal sleep tendencies, e.g., excessive daytime sleepiness or disturbed nocturnal sleep. Related diagnostic testing is covered if the patient has inappropriate sleep episodes or attacks, for example, while driving, in the middle of a meal, or in the middle of a conversation. Other examples include amnesiac episodes or continuous disabling drowsiness. Ordinarily, for a diagnosis of narcolepsy to be made, at least three naps are required. The diagnosis can be confirmed by polysomnography or Multiple Sleep Latency Testing. If more than three naps are claimed, there must be persuasive medical evidence to justify the necessity for additional test(s).

B. Sleep Apnea
This is a potentially lethal condition where the patient stops breathing during sleep. Three types of sleep apnea have been described (central, obstructive and mixed). The nature of the apnea episodes can be documented by appropriate diagnostic testing. Sleep apnea can be diagnosed by a single polysomnogram, including EEG leads, for a minimum of 6 hours. CPT 2005 describes sleep testing as
Sleep studies and polysomnography refer to the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for 6 or more hours with physician review, interpretation and report. The studies are performed to diagnose a variety of sleep disorders and to evaluate a patient's response to therapies such as, nasal continuous positive airway pressure (NCPAP).

C. Impotence
Polysomnography and Sleep Studies for impotence are not addressed in this policy.

D. Parasomnia
Parasomnias are a group of conditions that represent undesirable or unpleasant occurrences during sleep. Behavior during these times can often lead to damage to the surroundings and injury to the patient or to others. Parasomnia may include conditions such as sleepwalking, night terrors, and rapid eye movement (REM) sleep behavior disorders. In many of these cases, the nature of these conditions may be established by careful clinical evaluation. Suspected seizure disorders as the possible cause of parasomnia are appropriately evaluated by standard or prolonged sleep EEG (electroencephalogram) studies. In cases where seizure disorders have been ruled out and in cases that present a history of repeated violent or injurious episodes during sleep, polysomnography may be useful in providing a diagnostic classification or prognosis.

E. Polysomnography for Chronic Insomnia is not covered.
Evidence at the present time is not convincing that polysomnography in a sleep disorder clinic for chronic insomnia provides definitive diagnostic data; or that such information is useful in patient treatment; or is associated with improved clinical outcome. The use of polysomnography for the diagnosis of patients with chronic insomnia is not covered under Medicare because it is not reasonable and necessary.

F. Coverage of Therapeutic Services:
Sleep disorder clinics may at times render therapeutic as well as diagnostic services. Therapeutic services may be covered in a hospital outpatient setting or in a freestanding facility provided that they meet the pertinent requirements for the particular type of services, are reasonable and necessary for the patient, and are performed under the direct supervision of a physician.

Most of the patients who undergo the diagnostic testing are not considered inpatients, although they may come to the facility in the evening for testing and then leave after their tests are over. The overnight stay is considered an integral part of these tests.

Polysomnography includes sleep staging which is defined to include a 4-12 lead electroencephalogram (EEG), electrooculogram (EOG), and a submental electromyogram (EMG). Additional parameters of sleep include electrocardiogram (ECG); airflow; ventilation and respiratory effort; gas exchange by oximetry, transcutaneous monitoring or end tidal gas analysis; extremity muscle activity and/or motor activity; extended EEG monitoring; continuous blood pressure monitoring; snoring; and body positions, etc. For a study to be reported as a polysomnogram, sleep must be recorded and staged. The study should be performed in a hospital, an independent diagnostic testing facility or a sleep laboratory, be attended by a trained technologist and must be an observed study.
Polysomnography may be indicated for snoring when an overnight oximetry indicates desaturation to below 90% greater than 5% of the time. A combined diagnostic/therapeutic (CPAP) study may be indicated.

Snoring and nasal obstructive signs and symptoms are not, in and of themselves, indications for polysomnography, however, they may be indications of sleep apnea when other findings are also present. Other causes of sleepiness should be ruled out via a sleepiness scale before performing a sleep study.

**Indications and Limitations:**
Polysomnography is performed to diagnose a variety of sleep disorders which include, but are not limited to daytime somnolence, reports of sleeping/napping during the day, falling asleep at work or when driving and witnessed apneic episodes.

Sleep studies may also be indicated to evaluate a patient's response to certain therapy, for example, CPAP, for snoring when an overnight oximetry indicates desaturation below 90% greater than 5% of the time.

For a study to be reported as a polysomnogram, sleep must be recorded and staged and must be attended.

**Polysomnography and Sleep Studies (L34176)**

**Coverage Indications, Limitations, and/or Medical Necessity**

**Abstract:**
Sleep complaints and disorders are widespread. Although approximately 40 million Americans suffer from chronic sleep disorders, 95% of these are undiagnosed and untreated. The aging process places elderly persons at risk for sleep disturbances as the amount of time spent in deeper levels of sleep diminishes. Many sleep disorders can be managed by primary care physicians; however, when abnormal sleep patterns are not easily explainable and further evaluation is necessary, sleep studies may be needed.

Normal nocturnal sleep in adults displays a consistent organization from night to night. Sleep consists of two distinct states: rapid eye movement (REM), also called dream sleep and non-rapid eye movement (NREM), which is divided into four stages. NREM stages 1 and 2 are referred to as light sleep and stages 3 and 4 as deep or slow-wave sleep. Dreaming occurs mostly in REM and to a lesser extent in NREM sleep. Sleep is a cyclic phenomenon, with four or five REM periods during the night accounting for about one-fourth of the total night's sleep (1 1/2 - 2 hours).

Sleep studies and polysomnography refer to the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for 6 or more hours with physician review, interpretation and report. The studies are performed to diagnose a variety of sleep disorders and to evaluate a patient’s response to therapies such as continuous positive airway pressure (CPAP). Polysomnography is distinguished from sleep studies by the inclusion of sleep staging.

Polysomnography must be performed in a facility-based sleep study laboratory, and not in the home or in a mobile facility.
Performance of home sleep testing is limited to FDA cleared devices furnished with adequate patient instruction and support to assure successful completion of the studies. Provision of the device, patient instruction and support can be provided by accredited sleep centers as well as Independent Diagnostic Testing Facilities and other entities that can demonstrate use of FDA approved devices, inspection of the devices, and the patient support activities required. The provider may be subject to post payment audit to document these activities.

Physician services related to home sleep testing are covered for the purpose of determining a diagnosis of OSA (obstructive sleep apnea) if:

- It is reasonable and necessary for the diagnosis of the patient’s condition
- It is performed for patients with a high pretest probability of moderate to severe OSA
- It is performed in conjunction with a comprehensive sleep evaluation
- It meets all other Medicare requirements

The DMACs (Durable Medical Equipment Medicare Administrative Contractors) are responsible for providing coverage guidance on CPAP devices. The DMACs have published a policy that requires standards of credentialing for individuals who interpret the sleep testing results that are required for coverage of CPAP.

“For all PAP devices, the sleep test (Type I - IV, Other) must be interpreted by a physician who holds either:

a) Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or
b) Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or

c) Completed residency or fellowship training by a program approved by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or

d) Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC) or the Joint Commission" (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

Polysomnography is defined to include, but is not limited to, the following:

- A 1-4 lead electroencephalogram (EEG) to measure global neural encephalographic activity using electrodes placed on the scalp
- Electrooculogram (EOG) to measure eye movements using electrodes placed near the outer canthus of each eye
- A submental electromyogram (EMG) to measure submental electromyographic activity using electrodes placed over the mentalis, submentalis muscle, and/or masseter regions
- Rhythm electrocardiogram (ECG) with two or three chest leads
- Nasal and/or oral airflow via mercury switches or by direct observation
- Ventilation and respiratory effort by chest-wall and abdominal movement measured using strain gauges, piezoelectric belts, inductive plethysmography, impedance or inductance pneumography, endoesophageal pressure, or by intercostal EMG
• Gas exchange (oxygen saturation (SpO2)) by oximetry, transcutaneous monitoring, or end-tidal gas analysis
• Extremity muscle activity, motor activity-movement using EMG
• Body positions via mercury switches or by direct observation
• Recordings of vibration (frequency and/or volume) may be recorded
• Transcutaneous CO2, esophageal pH, penile tumescence, and bipolar EEG

Multiple sleep latency testing (MSLT) involves several 20-minute nap opportunities offered at 2-hour intervals. MSLT objectively assesses sleep tendency by measuring the number of minutes it takes the patient to fall asleep. Conversely, the maintenance of wakefulness test (MWT) requires the patient to try to stay awake. MSLT is the better test for demonstration of sleep-onset REM periods, a determination that is important in establishing the diagnosis of narcolepsy. To insure validity, proper interpretation of the MSLT can only be made following a polysomnography performed on the preceding night.

Sleep disorder clinics are facilities in which certain conditions are diagnosed through the study of sleep. Such clinics are for diagnosis, therapy, and research. Sleep disorder clinics may provide some diagnostic or therapeutic services that are covered under Medicare. These clinics may be affiliated either with a hospital or a freestanding facility. Whether a clinic is hospital-affiliated or freestanding, coverage for diagnostic services under some circumstances is covered under provisions of the law different from those for coverage of therapeutic services.

For a study to be reported as a polysomnogram, sleep must be recorded and staged.

Indications:
A. Criteria for Coverage of Diagnostic Tests

All reasonable and necessary diagnostic tests given for the medical conditions listed in subsection B are covered when the following criteria are met:
• The clinic is either affiliated with a hospital or is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder clinics may be covered even in the absence of direct supervision by a physician;
• Patients are referred to the sleep disorder clinic by their attending physicians, and the clinic maintains a record of the attending physician’s orders; and
• The need for diagnostic testing is confirmed by medical evidence, e.g., physician examinations and laboratory tests.

Diagnostic testing that is duplicative of previous testing done by the attending physician to the extent the results are still pertinent is not covered because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

B. Medical Conditions for Which Testing is Covered

Diagnostic testing is covered only if the patient has the symptoms or complaints of one of the conditions listed below. Most of the patients who undergo the diagnostic testing are not considered
inpatients, although they may come to the facility in the evening for testing and then leave after testing is over. The overnight stay is considered an integral part of these tests.

1. Narcolepsy - This term refers to a syndrome that is characterized by abnormal sleep tendencies, e.g., excessive daytime sleepiness or disturbed nocturnal sleep. Related diagnostic testing is covered if the patient has inappropriate sleep episodes or attacks (e.g., while driving, in the middle of a meal, in the middle of a conversation), amnesiac episodes, or continuous disabling drowsiness. The sleep disorder clinic must submit documentation that this condition is severe enough to interfere with the patient’s well-being and health before Medicare benefits may be provided for diagnostic testing. Ordinarily, a diagnosis of narcolepsy can be confirmed by three sleep naps. If more than three sleep naps are claimed, persuasive medical evidence justifying the medical necessity for the additional test(s) [will be required].

The diagnosis of narcolepsy is usually confirmed by an overnight sleep study (polysomnography) followed by a multiple sleep latency test (MSLT). The following measurements are normally required to diagnose narcolepsy:
- Polysomnographic assessment of the quality and quantity of nighttime sleep;
- Determination of the latency of the first REM episode;
- MSLT; and
- The presence of REM-sleep episodes.

Initial polysomnography and MSLT occasionally fail to identify narcolepsy. Repeat polysomnography may be indicated:
- if the first study is technically inadequate due to equipment failure;
- if the subject could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;
- if initiation of therapy or confirmation of the efficacy of prescribed therapy is needed; or
- if the results were inconclusive or ambiguous.

2. Sleep Apnea - This is a potentially lethal condition where the patient stops breathing during sleep. Three types of sleep apnea have been described (central, obstructive, and mixed). The nature of the apnea episodes can be documented by appropriate diagnostic testing. Ordinarily, a single polysomnogram and electroencephalogram (EEG) can diagnose sleep apnea. If more than one such testing session is claimed,… persuasive medical evidence justifying the medical necessity for the additional tests [will be required].

For additional instruction related to Continuous Positive Airway Pressure, (CPAP) Therapy for Obstructive Sleep Apnea (OSA) refer to coverage criteria and the definition of CPAP found in the CMS Manual System, Pub 100-03, Medicare National Coverage Determinations (Internet Only Manual).

Sleep apnea may be due to an occlusion of the airway (obstructive apnea), absence of respiratory effort (central sleep apnea) or a combination of these factors (mixed sleep apnea).

Obstructive sleep apnea (OSA) may be caused by one of the following:
- Reduced upper airway caliber due to obesity;
- Adenotonsillar hypertrophy;
• Mandibular deficiency;
• Macroglossia;
• Upper airway tumor;
• Excessive pressure across the collapsible segment of the upper airway;
• Activity of the muscles of the upper airway insufficient to maintain patency.

An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criterion using the Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) are met:
- AHI or RDI greater than or equal to 15 events per hour, or
- AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

The AHI is equal to the average number of episodes of apnea and hypopnea per hour. The RDI is equal to the average number of respiratory disturbances per hour.

The AHI or RDI is calculated on the average number of events per hour. If the AHI or RDI is calculated based on less than two hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at a minimum the number of events that would have been required in a two hour period.

These tests are recorded by polysomnography or by sleep testing devices that are unattended in or out of a sleep lab facility or attended in a sleep lab facility using a FDA approved Type II, III, or IV portable device recording at least 3 channels using actual recorded hours of sleep.

CPAP [Continuous Positive Airway Pressure] is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

The use of CPAP devices is covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adult patients with OSA if either of the AHI criteria mentioned above are met.

A positive diagnosis for OSA for the coverage of CPAP must include a clinical evaluation and a positive:
- attended PSG (polysomnogram) performed in a sleep laboratory; or
- unattended HST (home sleep test) with a Type II home sleep monitoring device; or
- unattended HST with a Type III home sleep monitoring device; or
- unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels.

For patients with severe and unambiguous obstructive sleep apnea, the initiation of treatment with nasal CPAP may be incorporated into the diagnostic study night. A "split-night" study (initial diagnostic polysomnogram followed by CPAP titration during polysomnography on the same night) may be an alternative to one full night of diagnostic polysomnography followed by a second night of titration as long as:
• CPAP titration is carried out for more than 3 hours; and
• Polysomnography documents that CPAP eliminates or nearly eliminates the respiratory events during REM and NREM sleep.

Repeat polysomnography for diagnosing sleep apnea requires documentation justifying the medical necessity for the repeated test.

Repeat polysomnography may be indicated:
• if the first study is technically inadequate due to equipment failure;
• if the subject could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;
• if the results were inconclusive or ambiguous; or
• if initiation of therapy or confirmation of the efficacy of prescribed therapy is needed.

Follow-up polysomnography or cardiorespiratory sleep studies are not routinely indicated for patients treated with CPAP whose symptoms continue to be resolved with CPAP treatment. Follow-up polysomnography or cardiorespiratory sleep studies may be indicated, however, for the following conditions:
• After substantial weight loss has occurred in patients on CPAP for treatment of sleep-related breathing disorders to ascertain whether CPAP is still needed at the previously titrated pressure;
• After substantial weight gain has occurred in patients previously treated with CPAP successfully, who are again symptomatic despite the continued use of CPAP, to ascertain whether pressure adjustments are needed; or
• When clinical response is insufficient or when symptoms return despite a good initial response to treatment with CPAP.

3. Parasomnia - Parasomnias are a group of conditions that represent undesirable or unpleasant occurrences during sleep. Behavior during these times can often lead to damage to the surroundings and injury to the patient or to others. Parasomnia may include conditions such as sleepwalking, sleep terrors, and rapid eye movement (REM) sleep behavior disorders. In many of these cases, the nature of these conditions may be established by careful clinical evaluation. Suspected seizure disorders as possible cause of the parasomnia are appropriately evaluated by standard or prolonged sleep EEG studies. In cases where seizure disorders have been ruled out and in cases that present a history of repeated violent or injurious episodes during sleep, polysomnography may be useful in providing a diagnostic classification or prognosis.

Normally, a clinical history, neurologic examination, and routine EEG obtained while the patient is awake and asleep are often sufficient to establish the diagnosis and permit the appropriate treatment of a sleep-related seizure disorder. In addition, common, uncomplicated, non-injurious parasomnias, such as typical disorders of arousal, nightmares, enuresis, somniloquy, and bruxism can usually be diagnosed by clinical evaluation alone.

Polysomnography is indicated to provide a diagnostic classification or prognosis when both of the following exist:
• When the clinical evaluation and results of standard EEG have ruled out a seizure disorder; and
• In cases that present a history of episodes during sleep that result in harm to the patient or others.
When polysomnography is performed for the diagnosis of parasomnias, the following measurements are obtained:
- Sleep-scoring channels (EEG, EOG, chin EMG);
- EEG using an expanded bilateral montage;
- EMG for body movements;
- Audiovisual recording; and
- Documented technologist observations.

C. Polysomnography for Chronic Insomnia Is **Not Covered**
Evidence at the present time is not convincing that polysomnography in a sleep disorder clinic for chronic insomnia provides definitive diagnostic data or that such information is useful in patient treatment or is associated with improved clinical outcome. The use of polysomnography for diagnosis of patients with chronic insomnia is **not covered** under Medicare because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

D. Coverage of Therapeutic Services
Sleep disorder clinics may at times render therapeutic as well as diagnostic services. Therapeutic services **may be covered** in a hospital outpatient setting or in a freestanding facility provided they meet pertinent requirements for the particular type of services and are reasonable and necessary for the patient, and are performed under the direct personal supervision of a physician.

**Limitations**
Diagnostic testing that is duplicative of previous sleep testing done by the attending physician to the extent that the previous results are still pertinent is **not covered**, because it is not reasonable and necessary if there have been no significant clinical changes in the patient's medical history since the previous study.

Polysomnography, cardiorespiratory sleep studies, and MSLT are **not covered** in the following situations:
- For the diagnosis of patients with chronic insomnia;
- To preoperatively evaluate a patient for laser-assisted uvulopalatopharyngoplasty without clinical evidence that obstructive sleep apnea is suspected;
- To diagnose chronic lung disease; (nocturnal hypoxemia in patients with chronic, obstructive, restrictive or reactive lung disease is usually adequately evaluated by oximetry; however, if the patient's sign/symptoms suggest a diagnosis of obstructive sleep apnea, polysomnography may be considered **medically necessary**);
- In cases where seizure disorders have not been ruled out;
- In cases of typical, uncomplicated and non-injurious parasomnias when the diagnosis is clearly delineated;
- For patients with a seizure disorder who have no specific complaints consistent with a sleep disorder;
- For patients with symptoms suggestive of periodic limb movement disorder or restless leg syndrome unless symptoms are suspected of being related to a **covered** indication;
- For the diagnosis of insomnia related to depression;
For the diagnosis of circadian rhythm sleep disorders (i.e., rapid time-zone change [jet lag], shift-work sleep disorder, delayed sleep phase syndrome, advanced sleep phase syndrome, and non-24 hour sleep/wake disorder).

For Medicare and Medicaid Determinations Related to States Outside of Nevada:
Please review Local Coverage Determinations that apply to other states outside of Nevada.
http://www.cms.hhs.gov/mcd/search

Important Note: Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

MEDICAID COVERAGE RATIONALE

Medicaid Services Manual (Accessed April 2017)

303.7 SLEEP STUDY SERVICES

303.7A SLEEP STUDY DESCRIPTION
According to the U.S. Department of Health and Human Services, National Institutes of Health (NIH), sleep studies are tests that measure how well someone sleeps and how the body responds to sleep problems. Sleep studies are necessary because untreated sleep disorders can raise risk for heart disease, high blood pressure, stroke, and other medical conditions. Sleep disorders have also been linked to an increased risk of injury, such as falling in the elderly and automobile accidents. Sleep studies, polysomnograms, and multiple sleep latency testing are limited to 2 services in a 12 month period without prior authorization. If the services exceed the limitations, a prior authorization is required from the QIO like vendor.

The following sleep study tests are covered benefits:

- Polysomnography (PSG) is the scientific evaluation of sleep that involves a physiologic recording of brain waves, oxygen level in blood, heart rate and breathing, and eye and leg movements.
- The multiple sleep latency test (MSLT) is performed to measure daytime sleepiness. Also known as a daytime nap study, the MSLT is the standard tool used to diagnose narcolepsy and idiopathic hypersomnia.

Sleep study services are performed with physician review, interpretation and report.

303.7C COVERAGE AND LIMITATIONS
Sleep studies are covered services in the following settings:

- A certified or accredited sleep disorder facility; or
- An in-home (unattended) setting in conjunction with a comprehensive sleep evaluation by a physician board certified in sleep medicine.

1. A licensed physician or other licensed professionals working within the scope of their practice must request the appropriate test.
2. The ordering provider is responsible for forwarding appropriate clinical data to the diagnostic facility.
3. The need for diagnostic testing is confirmed by medical evidence, e.g., patient history, physician examination and other laboratory type tests.

4. Polysomnography (PSM) minimum requirements include the following:
   a. EEG;
   b. Electro-oculography (EOG); and
   c. EMG.

5. Additional parameters of sleep which may be monitored include:
   a. EKG;
   b. Airflow;
   c. Ventilation and respiratory effort;
   d. Gas exchange by oximetry, transcutaneous monitoring, or end tidal gas analysis;
   e. Extremity muscle activity, monitor activity-movement;
   f. Extended EEG monitoring;
   g. Penile tumescence;
   h. Gastroesophageal reflux;
   i. Continuous blood pressure monitoring;
   j. Snoring; and
   k. Body positions, etc.

5. A PSG must be recorded and staged.

6. MSLT’s are **covered only** when symptoms suggest a diagnosis of narcolepsy.

### 303.7D UNATTENDED SLEEP STUDIES

1. Portable monitoring (PM) for the diagnosis of obstructive sleep apnea (OSA) should be performed only in conjunction with a comprehensive sleep evaluation.

2. Clinical sleep evaluations following PM must be supervised and evaluated by a physician board certified in sleep medicine.

3. PM may be used as an alternative to PSG for the diagnosis of OSA in recipients with a high pretest probability of moderate to severe OSA.

4. PM should not be used for the following recipients:
   a. with significant comorbid medical conditions that may degrade the accuracy of PM, including moderate to severe pulmonary disease, neuromuscular disorders, asthma, stroke, severe hypertension or congestive heart failure.
   b. suspect of having other sleep disorders, including central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders or narcolepsy.

5. PM should not be used for general screening of asymptomatic recipients.

6. PM may be indicated for the diagnosis of OSA in recipients for whom in-laboratory PSG is not possible by virtue of immobility, safety, or critical illness.

7. At a minimum, the PM must record airflow, respiratory effort, and blood oxygenation. The type of biosensors used to monitor these parameters for in-laboratory PSG are recommended for use in PM.

8. Unattended sleep studies are considered **medically necessary** using one of the following diagnostic techniques for recipients with symptoms suggestive of OSA when the home sleep study is used as part of a comprehensive sleep evaluation:
   a. Sleep monitoring using a Type II device, minimum of seven channels (e.g. electroencephalogram (EEG), electrooculogram (EOG), electromyogram (EMG), electrocardiogram (ECG), airflow, respiratory effort, oxygen saturation);
b. Sleep monitoring using a Type III device, minimum of four monitored channels including ventilation or airflow (at least two channels of respiratory movement or airflow), heart rate or ECG, and oxygen saturation; or
c. Sleep monitoring using a Type IV device, measuring at least three channels. Type IV devices must allow channels that allow direct calculation of an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) as the result of measuring airflow or thoracoabdominal movement.

9. An experienced sleep technician, sleep technologist or appropriately trained healthcare provider must perform the application of PM sensors or directly educate the recipient in correct application of the sensors.

10. Due to the known rate of false negative PM tests, in-laboratory PSG should be performed in cases where PM is technically inadequate or fails to establish the diagnosis of OSA in recipients with a high pretest probability.

11. If a PM test is technically inadequate or does not provide the expected result, in-laboratory PSG should be performed. Documentation supporting medical necessity for the repeat services must be clearly documented in the recipient’s medical record.

303.7E NON-COVERED SLEEP STUDY SERVICES
1. Actigraphy and SleepStrip® are considered investigational/experimental and are not covered benefits.
2. Repeat studies are not covered when documentation for a repeat study does not indicate medical necessity (e.g. no new clinical documentation indicating the need for a repeat study).

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 ≥ 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 PSG (≥ 7 channels) in a laboratory setting
- Type 2: full unattended PSG (≥ 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. Additional information can be found at [http://www.aasmnet.org/Resources/PracticeParameters/Outofcenter.pdf](http://www.aasmnet.org/Resources/PracticeParameters/Outofcenter.pdf) (Accessed April 2017).

**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 PSG. The reported 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 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 co-sponsored 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 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/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 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:  

**Single-Night versus Multiple-Night Home Sleep 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 (ARESTM) 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 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 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 "AHIligh" (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 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 ± 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 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® , 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+5.2 kg m⁻², mean pressure 16.4 cm H₂O) 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+1.8 cmH₂O, 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**

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 (Hayes, 2010; updated 2014; archived 2015).

**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)**

In a 2005 practice parameter, AASM considers PSG the "gold standard" for the evaluation of sleep and sleep related breathing. However, the guidelines caution 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. AASM also states that a split-night study (initial diagnostic PSG followed by CPAP 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 ≥ 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, AASM released updated clinical guidelines on the use of unattended portable monitors, essentially, at-home use, for diagnosing OSA in adults (Collop et al., 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 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)


The FDA has approved several home sleep testing devices as ventilatory effort recorders under the 510(k) premarking notification process. See the following website for more information (use product code MNR). [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). Accessed April 2017.

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

Examples include:

The FDA has cleared for marketing a number of different APAP devices under the 510(k) premarking notification 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. See the following website for more information (use product code BZD): [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). Accessed April 2017.

**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).

### 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 and Coverage Determination Guidelines may apply.
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<th>CPT Code</th>
<th>Description</th>
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<td>0381T</td>
<td>External heart rate and 3-axis accelerometer data recording up to 14 days to assess changes in heart rate and to monitor motion analysis for the purposes of diagnosing nocturnal epilepsy seizure events; includes report, scanning analysis with report, review and interpretation by a physician or other qualified health care professional</td>
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<td>Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist</td>
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<td>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</td>
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<td>Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording).</td>
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<td>Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness</td>
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Attended Polysomnography for Evaluation of Sleep Disorders

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<td>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</td>
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### REFERENCES


POLICY HISTORY/REVISION INFORMATION

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Corporate Medical Affairs Committee

The foregoing Health Plan of Nevada/Sierra Health & Life Health Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.