

Sleep Studies

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[Instructions for Use](#)

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Related Community Plan Policies
<ul style="list-style-type: none"> Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements Obstructive and Central Sleep Apnea Treatment
Commercial Policy
<ul style="list-style-type: none"> Sleep Studies

Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Idaho	Sleep Studies (for Idaho Only)
Indiana	None
Kansas	Sleep Studies (for Kansas Only)
Kentucky	Sleep Studies (for Kentucky Only)
Nebraska	Sleep Studies (for Nebraska Only)
New Jersey	Sleep Studies (for New Jersey Only)
New Mexico	Sleep Studies (for New Mexico Only)
North Carolina	Sleep Studies (for North Carolina Only)
Ohio	Sleep Studies (for Ohio Only)
Pennsylvania	None
Tennessee	None

Coverage Rationale

Home Sleep Apnea Testing

Home Sleep Apnea Testing (HSAT), using a portable monitor, is medically necessary for evaluating adults with suspected **Obstructive Sleep Apnea (OSA)**. Where HSAT is indicated, an autotitrating Positive Airway Pressure (APAP) device is an option to determine a fixed PAP pressure.

Note: Performing a repeat HSAT is not recommended when an initial test is negative, inconclusive, or technically inadequate, due to the higher likelihood that a second test will also be negative, inconclusive, or technically inadequate. Therefore, after a single negative, inconclusive, or technically inadequate HSAT result, performance of attended full-channel polysomnography is strongly recommended (Kapur et al., 2017).

Attended Full-Channel Polysomnography, Performed in a Healthcare Facility or Laboratory Setting

For the state of Missouri, refer to [Additional State Considerations](#).

Suspected Obstructive Sleep Apnea

Attended full-channel Polysomnography is medically necessary for evaluating individuals with suspected OSA when:

- Results of previous (within the past 12 months) HSAT are negative, indeterminate, or technically inadequate to make a diagnosis of OSA (Kapur et al., 2017; Centers for Medicare and Medicaid Services); or
- Individual is a child or adolescent (i.e., less than 18 years of age); or
- Individual is known to have one or more of the following comorbid medical conditions that prohibits the use of a HSAT:
 - Significant [Chronic Pulmonary Disease](#) as defined by a forced expiratory volume (FEV1)% predicted of < 60 (Pellegrino et al., 2005)
 - Progressive neuromuscular disease/neurodegenerative disorder (examples include but are not limited to Parkinson's disease, myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease, and history of stroke with persistent neurological sequelae)
 - Moderate to severe heart failure [[New York Heart Association class III or IV](#) (NYHA, 1994)] or left ventricular ejection fraction ≤ 40 (Yancy et al., 2013; Yancy et al., 2017)
 - Body mass index (BMI) > 50 (DeMaria et al., 2007; Blackstone and Cortés, 2010)
 - [Obesity Hypoventilation Syndrome](#)
 - Documented ongoing epileptic seizures in the presence of symptoms of sleep disorder
 - Chronic opiate medication use (> 3 months) (Dowell et al., 2022)

Also, refer to the [Attended Repeat Testing](#) section below.

Other Conditions

Attended full-channel Polysomnography is medically necessary following an appropriate clinical assessment either because OSA has been excluded, OSA has been adequately treated, or documented symptoms suggest one of the following conditions:

- [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 by appropriate clinical assessment (also refer to the [Daytime Sleep Studies](#) section below)
- [Central Sleep Apnea](#)

Implantable Hypoglossal Nerve Stimulator

Attended full-channel Polysomnography is medically necessary to rule out Central Sleep Apnea prior to implantation and/or calibration of an implantable hypoglossal nerve stimulator, when the device is indicated. Refer to the Medical Policy titled [Obstructive and Central Sleep Apnea Treatment](#) for implantable hypoglossal nerve stimulator indications.

Other Studies

The following studies are not medically necessary due to insufficient evidence of efficacy:

- Attended full-channel Polysomnography for evaluating any of the following conditions:
 - [Circadian Rhythm Disorders](#)
 - Depression
 - [Insomnia](#)
- Actigraphy for any sleep disorders

Daytime Sleep Studies

Note: The following sleep studies may be performed during the night if necessary to match an individual's normal sleep pattern.

Multiple Sleep Latency Testing (MSLT) is medically necessary for evaluating suspected Narcolepsy or idiopathic [Hypersomnia](#) when other causes of Excessive Sleepiness have been excluded by appropriate clinical assessment.

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:

- Sleep Studies
- Sleep Studies (Pediatric)

[Click here to view the InterQual® criteria.](#)

Maintenance of Wakefulness Testing (MWT) is medically necessary for evaluating the following:

- An adult who is unable to stay awake, resulting in a safety issue; or
- Assessing response to treatment in adults with sleep disorders

MWT is unproven and not medically necessary in children and adolescents less than 18 years of age.

Abbreviated daytime sleep studies (e.g., PAP-Nap) are not medically necessary due to insufficient evidence of efficacy.

Attended PAP Titration

When an individual meets the above [criteria](#) for an attended full-channel Polysomnography sleep study, the following are medically necessary:

- A split-night sleep study performed in a healthcare facility or laboratory setting for diagnosis and PAP titration; or
- A full night study for PAP titration, when a split-night sleep study is inadequate or not feasible and the individual has a confirmed diagnosis of OSA

Also, refer to the [Attended Repeat Testing](#) section below.

Attended Repeat Testing

Repeat attended full-channel polysomnography and repeat PAP titration are medically necessary in the following circumstances:

- Individuals who have persistent, recurrent, or new symptoms, despite documented appropriate current treatment or PAP therapy (e.g., equipment failure, improper mask fit, pressure leaks, unsuccessful titration, inadequate pressure, and medical problems including nasal congestion have been addressed and appropriately managed); or
- Individuals who have experienced a clinically significant weight loss or gain ($\geq 10\%$) or changes in cardiovascular disease since the last study (Caples et al., 2021; Peppard et al., 2000).

Repeat Testing for Oral Appliance Adjustments

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

Additional State Considerations

State	State Considerations
Missouri	<p>Attended full-channel nocturnal Polysomnography, when performed in an outpatient hospital health care facility, must be medically necessary.</p> <p>The following will be taken into account to determine whether an attended full-channel nocturnal Polysomnography is medically necessary to be performed in a more cost-effective setting:</p> <ul style="list-style-type: none">• State Medicaid contract• Any federal or state requirements• Geographic availability of an in-network provider• Laboratory capability <p>*This applies to CPT codes 95805, 95807, 95808, 95810, and 95811.</p>

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled [Medical Records Documentation Used for Reviews](#).

Definitions

Actigraphy: A measurement of physical activity, typically via a wrist-worn movement sensor, employed to estimate sleep and wakefulness based on relative levels of physical inactivity and activity (ICSD-3-TR, 2023).

Apnea: The cessation of airflow ($\geq 90\%$ decrease in Apnea sensor excursions compared to baseline) lasting at least 10 seconds. Apneas are classified as obstructive, central, or mixed based on the pattern of respiratory effort:

- An Obstructive Apnea is associated with continued or increased inspiratory effort throughout the entire period of absent airflow.
- A Central Apnea is associated with absent inspiratory effort throughout the entire period of absent airflow.
- Mixed Apneas are associated with absent inspiratory effort in the initial portion of the event, followed by resumption of inspiratory effort in the second portion of the event.

[American Academy of Sleep Medicine (AASM) Scoring Manual, 2023]

Apnea Hypopnea Index (AHI): The number of Apneas plus the number of Hypopneas during the entire sleeping period, times 60, divided by total sleep time in minutes; unit: event per hour (AASM Scoring Manual, 2023).

Central Disorders of Hypersomnolence: Sleep disorders in which the primary complaint is Excessive Daytime Sleepiness not caused by a Circadian Rhythm sleep-wake disorder or disturbed sleep due to another untreated sleep disorder such as sleep Apnea (ICSD-3-TR, 2023).

Central Sleep Apnea (CSA): CSA syndromes are characterized by sleep disordered breathing associated with diminished or absent respiratory effort, coupled with the presence of symptoms including Excessive Daytime Sleepiness, frequent nocturnal awakenings, or both (Aurora et al., 2012).

Chronic Pulmonary Disease (CPD): A method of categorizing the severity of lung function impairment based on forced expiratory volume (FEV₁)% predicted is provided in the below table. Severity of any spirometric abnormality based on the forced expiratory volume in one second (FEV₁).

Degree of Severity	FEV ₁ % Predicted
Mild	> 70
Moderate	60-69
Moderately Severe	50-59
Severe	35-49
Very Severe	< 35

(Pellegrino et al., 2005)

Circadian Rhythm: Biological oscillation, with a periodicity near 24 hours, which is clock-drive (i.e., not caused by external or non-circadian clock factors (ICSD-3-TR, 2023).

Circadian Rhythm Sleep-Wake Disorders: Sleep disorders caused by disturbances of the internal circadian timing system itself, or its entrainment mechanisms, or a misalignment between the timing of the individual's circadian sleep-wake propensity and the 24-hour social and physical environments (e.g., sleep episodes scheduled entirely or in part during a phase of circadian alertness promotion) (ICSD-3-TR, 2023).

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 an individual's assessment of the likelihood of falling asleep in certain situations commonly encountered in daily life. Refer to the following website for further information:

<http://epworthsleepinessscale.com/about-the-ess/>. (Accessed July 17, 2025).

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

Home Sleep Apnea Testing (HSAT): 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 individuals undergo these tests (AASM Style Guide, 2015). Adequate HSAT occurs over a minimum of four hours and includes a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry (Kapur et al., 2017). HSAT is also referred to as out-of-center sleep testing or portable monitoring.

Hypersomnia (Excessive Sleepiness): A disorder characterized by Excessive Sleepiness (e.g., idiopathic Hypersomnia) (ICSD-3-TR, 2023).

Hypersomnolence: Excessive Sleepiness during the normal wake period or increased sleep duration (ICSD-3-TR, 2023).

Hypopnea: An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in airflow and with at least a 3% decrease in oxygen saturation from pre-event baseline or the event is associated with an arousal (AASM Scoring Manual, 2023).

Insomnia: A persistent difficulty with sleep initiation or maintenance that is associated with concern, dissatisfaction, or perceived daytime impairment, such as fatigue, decreased mood or irritability, general malaise, or cognitive impairment (ICSD-3-TR, 2023).

Maintenance of Wakefulness Test (MWT): A daytime sleep study that measures the ability to stay awake in nonstimulating conditions for a defined period of time (Littner et al., 2005; Krahn et al., 2021).

Monitoring Time: Total recording time minus periods of artifact and time the individual was awake as determined by Actigraphy, body position sensor, respiratory pattern, or individual diary (AASM Scoring Manual, 2023).

Multiple Sleep Latency Test (MSLT): A daytime sleep study that measures physiological sleep tendency under standardized conditions in the absence of external alerting factors (Littner et al., 2005; Krahn et al., 2021).

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-TR, 2023). Narcolepsy type 2 is characterized by Excessive Daytime Sleepiness, without cataplexy, with unmeasured or normal cerebrospinal fluid hypocretin-1 levels (ICSD-3-TR, 2023).

New York Heart Association (NYHA) Heart Failure Classification (NYHA, 1994):

- I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Obesity Hypoventilation Syndrome (OHS): A breathing disorder characterized by obesity (BMI ≥ 30 kg/m²) and daytime hypercapnia (arterial PaCO₂ ≥ 45 mmHg) that cannot be entirely 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-TR, 2023).

Obstructive Sleep Apnea (OSA): The AASM defines Obstructive Sleep Apnea as a sleep-related breathing disorder that involves a decrease or complete halt in airflow despite an ongoing effort to breathe. 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 /hour.

PAP-Nap: PAP-Nap is a daytime, abbreviated cardio-respiratory sleep study for individuals 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 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 sleep-wake transitions. Parasomnias are characterized by 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-TR, 2023). Also refer to [RBD](#).

Periodic Limb Movement Disorder (PLMD): A sleep disorder characterized by periodic episodes of repetitive, stereotyped limb movements that occur during sleep, in conjunction with clinical sleep disturbance or daytime impairment that cannot be accounted for by another primary sleep disorder or other etiology (ICSD-3-TR, 2023).

Periodic Limb Movements of Sleep (PLMS): Movements of the limbs during sleep occurring with a specified frequency, duration, and amplitude (AASM Scoring Manual, 2023).

Polysomnogram (Attended): A laboratory-based sleep study that uses multiple channels to record a wide range of physiological information, including brain activity, eye movements, body movements, breathing, and heart rate (American Thoracic Society, 2015; updated 2019).

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 and EMG abnormalities during REM sleep (ICSD-3-TR, 2023).

Respiratory Disturbance Index (RDI): The number of Apneas plus the number of Hypopneas plus the number of Respiratory Effort-Related Arousals during the entire sleeping period, times 60, divided by total sleep time in minutes; unit: events per hour (AASM Scoring Manual, 2023).

Respiratory Effort-Related Arousal (RERA): A sequence of breaths characterized by increasing respiratory effort (esophageal manometry), 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, 2023).

Respiratory Event Index (REI): Total number of respiratory events scored during the entire sleeping period, times 60, divided by Monitoring Time in minutes; unit: events per hour. The REI is used for HSAT and is a surrogate for AHI (AASM Scoring Manual, 2023).

Restless Legs Syndrome (RLS)/Willis-Ekbom Disease: RLS is a sensorimotor disorder characterized by a complaint of a strong, nearly irresistible urge to move the limbs. This urge to move is often, but not always, accompanied by other uncomfortable sensations felt in the limbs or by a feeling that is simply difficult or impossible to describe. Although the legs are most prominently affected, these sensations may occur in the arms as well (ICSD-3-TR, 2023).

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 federal, state, or contractual requirements 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 Guidelines may apply.

CPT Code	Description
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
*95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)
*95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
*95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
*95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
*95811	Polysomnography; age 6 years or older, 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

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

Description of Services

Sleep disorders are conditions that affect an individual's normal sleep patterns and can have an impact on quality of life. One of the most common sleep disorders is Obstructive Sleep Apnea (OSA), a condition in which a person stops breathing during sleep due to a narrowed or closed airway. Symptoms of OSA include daytime sleepiness, loud snoring and breathing interruptions or awakenings due to gasping or choking. If left untreated, OSA can lead to serious health consequences such as hypertension, heart disease, stroke, insulin resistance, and obesity. Other sleep disorders include Central Sleep Apnea, Periodic Limb Movement Disorder (PLMD), Narcolepsy, Restless Legs Syndrome, Parasomnias, Circadian Rhythm Disorders, 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; updated 2019).

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. PSG may also be used to assess and adjust the treatment plan (American Thoracic Society, 2015; updated 2019).

Sleep studies conducted during the day include the Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT). MSLT is performed after a PSG to measure daytime sleepiness and is most often used to diagnose Narcolepsy and idiopathic Hypersomnia. MWT is performed to assess the ability to stay awake in nonstimulating conditions for a defined period of time (Krahn et al., 2021). Evidence is insufficient to specify a recommended protocol for the MWT in children and adolescents (Maski et al., 2024).

Additional Information

According to the 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 an individual 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 individual'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 /hour

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 <https://aasm.org/resources/practiceparameters/outofcenter.pdf> (Accessed July 17, 2025).

Clinical Evidence

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 American Academy of Sleep Medicine (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.

For details regarding specific devices, refer to the full text article at:

<https://aasm.org/resources/practiceparameters/outofcenter.pdf> (Accessed July 17, 2025).

Khawaja et al. (2010) reviewed 114 consecutive full-night PSGs (FN-PSG) on individuals with OSA and compared the AHI from the first two hours (2 hour-AHI) and three hours (3 hour-AHI) of sleep with the "gold standard" AHI from FN-PSG (FN-AHI), considering OSA present if FN-AHI $> = 5$. The authors found that the AHI derived from the first two or three

hours of sleep is of sufficient diagnostic accuracy to rule-in OSA at an AHI threshold of 5 in individuals suspected of having OSA. This study suggests that the current recommended threshold for split-night studies (AHI \geq 20 to 40) may be revised to a lower number, allowing for more efficient use of resources.

Using a cohort study design, Collen et al. (2010) evaluated 400 consecutive individuals presenting for follow-up four to six weeks after initiating CPAP therapy. Among the cohort, 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 individuals 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 individuals with OSA.

Single-Night Versus Multiple-Night Home Sleep Apnea Testing

In a systematic review and meta-analysis, Roeder et al. (2020) evaluated the night-to-night variability of respiratory events in adults with suspected or diagnosed OSA who underwent more than one diagnostic sleep study. A total of 24 studies, comprising 3,250 participants were included: 14 prospective observational studies, eight retrospective observational studies and two randomized controlled trials (RCTs) reporting only data from the control group. Outcome measures included night-to-night variability of respiratory events reported on a group or intraindividual level. The authors also analyzed the mean AHI difference between the first and second sleep study. Results did not demonstrate clinically relevant night-to-night variability of respiratory events between two sequential nights on a group level; however, the data suggested intraindividual variability. On average, 41% of all participants showed changes of respiratory events > 10 /hour from night to night. Forty-nine percent of participants changed OSA severity class (severity thresholds at 5/hour, 15/hour, and 30/hour) at least once in sequential sleep studies. On average, AHI values were lower in the first night as compared with the second night with an estimated mean change of -1.70 /hour. A subgroup analysis between sleep study locations (i.e., hospital versus home) revealed that mean AHI differences between two sleep studies were greater in the in-hospital group, but the difference did not reach statistical significance on a group level. Limitations include large heterogeneity among studies, observational study designs, high risk of bias, and the use of different sleep study devices and scoring rules across studies. The authors noted a need for comparative effectiveness studies to determine the effect of repeated sleep studies on clinical outcomes. (Publications by Fietze 2004, Stepnowsky 2004, Davidson 2003 and Quan 2002, which were previously cited in this policy, are included in this systematic review.)

Levendowski et al. (2009) investigated the variability of AHI obtained by PSG and by in-home portable recording in 37 individuals with untreated mild to moderate OSA at a four- to six-month interval. The in-home studies were performed with Apnea Risk Evaluation System (ARES™) Unicorder. When comparing the test-retest AHI and apnea index (AI), the in-home results were more highly correlated ($r = 0.65$ and 0.68) than the comparable PSG results ($r = 0.56$ and 0.58). The in-home results provided approximately 50% less test-retest variability than the comparable PSG AHI and AI values. Both the overall PSG AHI and AI showed a substantial bias toward increased severity upon retest (8 and 6 events/hour 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). Individuals biased toward more time supine during the initial PSG. No trends in time supine for in-home studies were noted.

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

Home-Based Versus In-Laboratory Diagnostic Testing

Comparative effectiveness research studies have shown that clinical outcomes of individuals with a high pretest probability for OSA who receive ambulatory management using portable-monitor testing have similar functional outcomes and adherence to CPAP treatment, compared to individuals managed with in-laboratory PSG.

An ECRI report summarized the literature surrounding evidence-based decision making in adults undergoing sleep studies. The evidence analysis considered selection criteria for home-based, laboratory-based, and hospital-based sleep studies while also considering safety and diagnostic accuracy. The overall evidence provided information on operation standards, selection criteria, and other important considerations for conducting a sleep study in inpatient and outpatient settings (ECRI, 2024).

Khor et al. (2023) conducted a systematic review evaluating the diagnostic performance of various portable devices used to assess OSA in adults. A total of 180 studies comparing portable diagnostic tests with type 1 PSG, and 10 comparing wearable devices and noncontact systems with portable PSG/PG were included. Most studies were prospective cross-sectional and single-center studies. Despite varying study designs and devices used, portable diagnostic tests were found to be sufficient for the initial screening of individuals at risk of OSA.

In a 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 three 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 individuals 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. Individuals in all three pathways demonstrated equivalent use of PAP despite differences in polysomnographic procedures, clinical education, and follow-up. The findings are, however, limited by the observational nature of the study, which could be subject to biases.

In a randomized controlled study involving 102 participants 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 one night of level three testing (Embletta) followed by one week of auto-CPAP therapy (Auto-Set) and three weeks of fixed-pressure CPAP based on the 95% pressure derived from the auto-CPAP device. After four weeks of CPAP therapy, there were no significant differences in daytime sleepiness (ESS), sleep quality, quality of life, blood pressure and CPAP adherence.

Non-inferiority of home APAP titration compared to manual laboratory titration was confirmed by McArdle et al. (2010). In this randomized controlled study involving 249 individuals 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 participants with a high likelihood of having OSA. After six weeks of treatment 40 participants 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.

Mulgrew et al. (2007) randomly assigned 68 high-risk individuals identified by a diagnostic algorithm to PSG or ambulatory titration by using a combination of auto-CPAP and overnight oximetry. After three 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.

A single-blind randomized controlled trial with 200 CPAP-naive participants 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).

Actigraphy

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

An ECRI report assessing actigraphy for evaluating adults with suspected or diagnosed narcolepsy concluded that the evidence from eight small diagnostic cohort studies was too limited in quantity and quality to validate actigraphy as an adjunct or alternative to conventional sleep studies for central hypersomnia. Only one study at high risk of bias reported on actigraphy's diagnostic accuracy. Six additional studies reported on metric agreement between actigraphy and

conventional sleep studies, but the studies did not permit conclusions because the findings were inconsistent and at high risk of bias (ECRI, 2025).

A Hayes review of abstracts suggests that there is not enough published peer-reviewed literature to evaluate the evidence related to stand-alone actigraphy for the evaluation of insomnia (Hayes, 2025a).

A Hayes review of abstracts suggests that there is not enough published peer-reviewed literature to evaluate the evidence related to stand-alone actigraphy for the evaluation of OSA (Hayes, 2025b).

Smith et al. (2018a) performed a systematic review of 81 studies comparing the use of actigraphy, sleep logs, and/or polysomnography. The results were used to support an AASM clinical practice guideline on the use of actigraphy in individuals with suspected or diagnosed sleep disorders or circadian rhythm sleep-wake disorders (Smith et al., 2018b). The authors present a detailed summary of the evidence including the quality of evidence and the balance of benefits and harms. Studies demonstrate that actigraphy provides consistent objective data that is often unique from patient-reported sleep logs for some sleep parameters in adult and pediatric individuals with certain sleep disorders; however, evidence demonstrating the impact on treatment decisions and improved clinical outcomes is needed.

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

PAP-Nap Test

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

Ulibarri et al. (2020) performed a retrospective chart review on 139 patients diagnosed with OSA (n = 116) or upper airway resistance syndrome (n = 23). All participants refused to proceed with either a full-night attended titration or an in-home trial of PAP but completed a PAP-Nap instead. The most common risk factors for PAP rejection were depression, insomnia, and claustrophobia, while the most common indications for PAP-Nap were general reluctance, anxiety, and claustrophobia. Although results showed that improvements in emotional aversion and motivation were associated with increased PAP use, the authors noted that randomized control trials are needed to assess the experiential component at the core of the PAP-Nap procedure and its efficacy in reversing early PAP rejecters.

In a pilot study, Krakow et al. (2008) assessed the impact of the PAP-Nap sleep study on adherence to PAP therapy among individuals with insomnia and 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 attention from mask or pressure sensations, and physiological exposure to PAP therapy during a 100-minute nap period. Individuals treated with the PAP-Nap test (n = 39) were compared to a historical control group (n = 60) of individuals with insomnia and SDB who did not receive the test. All 99 individuals with insomnia 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 individuals completing the PAP-Nap, 90% completed overnight titrations, compared with 63% in the historical control group. Eighty-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.

Clinical Practice Guidelines

American Academy of Sleep Medicine (AASM)

Maski et al. (2024) reviewed the literature on the MSLT and MWT for the diagnosis and management of central disorders of hypersomnolence in children and adolescents. There was insufficient evidence to specify a recommended protocol for the MWT in this population. Therefore, the protocol paper provided guidance to health care providers who order, sleep specialists who interpret, and technical staff who administer the MSLT. Specific changes recommended for pediatric MSLT protocols include the following:

- Provision of a minimum of 7 hours of sleep (with a minimum 8-hour recording time) on PSG the night before the MSLT, ideally meeting age-based needs.
- Use of clinical judgment to guide the need for sleep-disordered breathing treatments before PSG-MSLT testing.
- Shared patient-health care provider decision-making regarding modifications in the protocol for children and adolescents with neurodevelopmental/neurological disorders, young age, and/or delayed sleep phase.

For MSLT and MWT in adults, see Krahn et al. (2021) noted below.

Krahn et al. (2021) updated AASM's protocols for the administration of the MSLT and MWT in adults. Although no evidence-based changes to the protocols were warranted, the task force made several changes based on consensus. These changes included guidance on patient preparation, medication and substance use, sleep prior to testing, test scheduling, optimum test conditions, and documentation.

An AASM clinical guidance statement (Caples et al., 2021) combined clinical evidence and expert opinion to make the following recommendations for follow-up PSG and HSAT in adult patients with OSA:

- Follow-up PSG or HSAT is not recommended for routine reassessment of asymptomatic patients with OSA on PAP therapy, however, follow-up PSG or HSAT can be used to reassess patients with recurrent or persistent symptoms, despite good PAP adherence.
- Follow-up PSG or HSAT is recommended to assess response to treatment with non-PAP interventions.
- Follow-up PSG or HSAT may be used if clinically significant weight gain or loss has occurred since diagnosis of OSA or initiation of its treatment.
- Follow-up PSG may be used for reassessment of sleep-related hypoxemia and/or sleep-related hypoventilation following initiation of treatment for OSA.
- Follow-up PSG or HSAT may be used in patients being treated for OSA who develop or have a change in cardiovascular disease.
- Follow-up PSG may be used in patients with unexplained PAP device-generated data.

Statements using “recommended” and “not recommended” indicate that a test is clearly useful or ineffective/harmful for most patients, respectively, based on a qualitative assessment of the available evidence and clinical judgement of the task force. Statements using “may be used” indicate that the evidence or expert consensus is less clear, either in favor or against the use of a testing option.

AASM clinical practice guidelines (Smith et al., 2018b) present recommendations for the use of actigraphy in patients with suspected or diagnosed sleep disorders or circadian rhythm sleep-wake disorders. In these guidelines, which consisted of a systematic review of the evidence, AASM made the following recommendations:

- AASM suggests that clinicians use actigraphy to estimate sleep parameters in adult patients with insomnia disorder. (Conditional)
- AASM suggests that clinicians use actigraphy in the assessment of pediatric patients with insomnia disorder. (Conditional)
- AASM suggests that clinicians use actigraphy in the assessment of adult patients with circadian rhythm sleep-wake disorder. (Conditional)
- AASM suggests that clinicians use actigraphy in the assessment of pediatric patients with circadian rhythm sleep-wake disorder. (Conditional)
- AASM suggests that clinicians use actigraphy integrated with home sleep apnea test devices to estimate total sleep time during recording (in the absence of alternative objective measurements of total sleep time) in adult patients suspected of sleep-disordered breathing. (Conditional)
- AASM suggests that clinicians use actigraphy to monitor total sleep time prior to testing with the Multiple Sleep Latency Test in adult and pediatric patients with suspected central disorders of hypersomnolence. (Conditional)
- AASM suggests that clinicians use actigraphy to estimate total sleep time in adult patients with suspected insufficient sleep syndrome. (Conditional)
- AASM recommends that clinicians not use actigraphy in place of electromyography for the diagnosis of periodic limb movement disorder in adult and pediatric patients. (Strong)

Conditional recommendations reflect a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients. A strong recommendation is one that clinicians should follow under most circumstances.

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

- Good Practice Statements:
 - Diagnostic testing for OSA should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up.
 - PSG is the standard diagnostic test for the diagnosis of OSA in adult patients in whom there is a concern for OSA based on a comprehensive sleep evaluation.
- Recommendations:
 - AASM recommends that clinical tools, questionnaires, and prediction algorithms not be used to diagnose OSA in adults, in the absence of PSG or HSAT. (Strong)
 - AASM recommends that PSG, or HSAT with a technically adequate device, be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA. (Strong)
 - AASM recommends that if a single HSAT is negative, inconclusive, or technically inadequate, PSG be performed for the diagnosis of OSA. (Strong)
 - AASM recommends that PSG, rather than HSAT, be used for the diagnosis of OSA in patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep-related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia. (Strong)
 - AASM suggests that, if clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for PSG be used for the diagnosis of OSA. (Weak)
 - AASM suggests that when the initial PSG is negative and clinical suspicion for OSA remains, a second PSG be considered for the diagnosis of OSA. (Weak)

Regarding multiple-night HSAT, AASM notes the adequacy of a single night HSAT performed for the diagnosis of OSA in the context of an appropriate clinical population and management pathway is supported by published evidence. AASM found two studies that evaluated the performance of multiple nights (three) of single channel HSAT device to the first night of recording. The studies found that recording over three consecutive nights may decrease the probability of insufficient data and marginally improve accuracy when compared against a single night of recording. However, the task force considered this evidence insufficient to establish the superiority of multiple-night HSAT protocol over a single-night HSAT protocol, as the studies only included a single channel recording and did not evaluate clinically meaningful outcomes or efficiency of care. Insufficient evidence exists to support routine performance of more than a single night's recording for HSAT. Home sleep apnea testing is less sensitive than PSG and a false negative could result in harm to the patient. Performing a repeat HSAT is not recommended when an initial test is negative, inconclusive, or technically inadequate, due to the higher likelihood that a second test will also be negative, inconclusive, or technically inadequate. There is also an increased risk that the patient will not complete the diagnostic process prior to a definitive diagnosis. Therefore, after a single negative, inconclusive or technically inadequate HSAT result, performance of a PSG is strongly recommended (Kapur et al., 2017).

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

An 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).

An AASM practice parameter and evidence review (Littner et al., 2005; Arand et al., 2005), regarding the clinical use of the MSLT and the MWT in adults, concluded the following:

- The MSLT is indicated as part of the evaluation of individuals with suspected narcolepsy to confirm the diagnosis.
- The MSLT may be indicated as part of the evaluation of individuals with suspected idiopathic hypersomnia to help differentiate idiopathic hypersomnia from narcolepsy.
- The MSLT is not routinely indicated in the initial evaluation and diagnosis of OSA 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 individual is suspected to have narcolepsy but earlier MSLT evaluation(s) did not provide polygraphic confirmation.
- The MWT may be indicated in individuals 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.

Department of Veterans Affairs (VA)/Department of Defense (DoD)

VA/DoD clinical practice guidelines for the management of chronic insomnia disorder and OSA are based on a systematic review of clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, the guidelines address various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation. For sleep studies, the guidelines provide the following recommendations:

- For diagnosis of clinically suspected OSA, the panel recommends diagnosis with PSG or HSAT. Strong
- For diagnosis of OSA in appropriate patients, the panel suggests HSAT as an alternative to in-laboratory PSG. Weak
- HSAT is not recommended, nor should it be performed, in patients with significant comorbid pulmonary, cardiovascular, or neuromuscular disease as these conditions may be associated with other sleep disordered breathing.
- For diagnosis of patients with a non-diagnostic HSAT, the panel recommends further sleep testing for OSA with in-lab PSG or HSAT. Strong

(Department of Veterans Affairs and Department of Defense, 2025)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Systems to record and analyze PSG information are cleared for marketing under the 510(k) premarketing notification process. Refer to the following website for more information (use product code OLV):

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm>. (Accessed July 17, 2025)

HSAT devices are cleared for marketing under the 510(k) premarketing notification process. Refer to the following website for more information (use product code MNR): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm>.

(Accessed July 17, 2025)

Actigraphy devices are cleared for marketing under the 510(k) premarketing notification process. Some actigraphy devices measure sleep-wake states, while others measure levels of physical activity. Search the following website by product name for more information: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm>.

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Policy History/Revision Information

Date	Summary of Changes
04/01/2026	<p>Template Update</p> <ul style="list-style-type: none"> Removed content/language pertaining to the state of Louisiana
02/01/2026	<p>Coverage Rationale</p> <p>Home Sleep Apnea Testing (HSAT)</p> <ul style="list-style-type: none"> Added notation to indicate performing a repeat HSAT is not recommended when an initial test is negative, inconclusive, or technically inadequate, due to the higher likelihood that a second test will also be negative, inconclusive, or technically inadequate; therefore, after a single negative, inconclusive, or technically inadequate HSAT result, performance of attended full-channel polysomnography is strongly recommended <p>Attended Full-Channel Polysomnography, Performed in a Healthcare Facility or Laboratory Setting</p> <p>Suspected Obstructive Sleep Apnea (OSA)</p> <ul style="list-style-type: none"> Revised coverage criteria for attended full-channel Polysomnography for evaluating individuals with suspected OSA; replaced criterion requiring “results of previous HSAT are negative, indeterminate, or technically inadequate to make a diagnosis of OSA” with “results of previous (<i>within the past 12 months</i>) HSAT are negative, indeterminate, or technically inadequate to make a diagnosis of OSA”

Date	Summary of Changes
	<p>Daytime Sleep Studies</p> <ul style="list-style-type: none"> Replaced language indicating “Multiple Sleep Latency Testing (MSLT) is medically necessary <i>when it is indicated by</i> suspected narcolepsy or idiopathic Hypersomnia and other cause of Excessive Sleepiness have been excluded by appropriate clinical assessment” with “Multiple Sleep Latency Testing (MSLT) is medically necessary <i>for evaluating</i> suspected Narcolepsy <i>when</i> other causes of Excessive Sleepiness have been excluded by appropriate clinical assessment” Revised language pertaining to medical necessity clinical coverage criteria; removed reference to the InterQual® CP: Procedures, Sleep Studies for Maintenance of Wakefulness Testing (MWT) <p>Attended Repeat Testing</p> <ul style="list-style-type: none"> Replaced language indicating “repeat attended full-channel polysomnography and repeat Positive Airway Pressure (PAP) titration are medically necessary for <i>certain</i> individuals who have persistent or new symptoms, despite documented appropriate current treatment or PAP therapy” with “repeat attended full-channel polysomnography and repeat Positive Airway Pressure (PAP) titration are medically necessary for individuals who have persistent, <i>recurrent</i>, or new symptoms, despite documented appropriate current treatment or PAP therapy” Added language to indicate repeat attended full-channel polysomnography and repeat PAP titration are medically necessary for individuals who have experienced a clinically significant weight loss or gain ($\geq 10\%$) or changes in cardiovascular disease since the last study <p>Medical Records Documentation Used for Reviews</p> <ul style="list-style-type: none"> Updated list of Medical Records Documentation Used for Reviews; added “for Attended Repeat Testing and/or appliance adjustment, in addition to the [listed documentation requirements], also include reason why repeat study should be performed” <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information Archived previous policy version CS098.AC

Instructions for Use

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