Sleep Studies

Policy Number: CS098.AA
Effective Date: October 1, 2023

Instructions for Use

Table of Contents **Page**

Related Community Plan Policies

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements
- Obstructive and Central Sleep Apnea Treatment

Commercial Policy

- Sleep Studies

Medicare Advantage Coverage Summary

- Sleep Apnea Diagnosis and Treatment

Application

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

State	Policy/Guideline
Indiana	None
Kentucky	Sleep Studies (for Kentucky Only)
Louisiana	None
Nebraska	None
New Jersey	Sleep Studies (for New Jersey 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.

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

For the states of Mississippi and Missouri, refer to Additional State Considerations.

Attended full-channel Polysomnography 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**
- 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, 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

Also, refer to the Attended Repeat Testing section below.

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

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. Refer to the Medical Policy titled Obstructive and Central Sleep Apnea Treatment for implantable hypoglossal nerve stimulator indications.

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 when it is indicated by all of the following:

- Suspected Narcolepsy or idiopathic Hypersomnia; and
- 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

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

Click here to view the InterQual® criteria.

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
- 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 for certain individuals who have persistent or new symptoms, despite documented appropriate current treatment or PAP therapy (e.g., equipment failure, improper mask fit, pressure leaks, unsuccessful titration, inadequate pressure, and medical problems including nasal congestion have been addressed and appropriately managed).

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

Additional State Considerations

State	State Considerations
Mississippi	**Attended full-channel nocturnal Polysomnography is medically necessary for evaluating individuals with suspected OSA.** *This applies to the following CPT codes: 95805, 95807, 95808, 95810, and 95811
Missouri	**Attended full-channel nocturnal Polysomnography, when performed in an outpatient hospital health care facility, must be medically necessary.** 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: • State Medicaid contract • Any federal or state requirements • Geographic availability of an in-network provider • Laboratory capability *This applies to the following CPT codes: 95805, 95807, 95808, 95810, and 95811

Definitions

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

Apnea: The cessation of airflow (≥ 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 daytime sleepiness not caused by disturbed nocturnal sleep or misaligned Circadian Rhythms (ICSD-3, 2014).

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

Chronic Pulmonary Disease (CPD): A method of categorizing the severity of lung function impairment based on forced expiratory volume (FEV_1) % predicted is provided in the below table. Severity of any spirometric abnormality based on the forced expiratory volume in one second (FEV_1).

Degree of Severity	FEV_1% Predicted
Mild	> 70
Moderate	60-69
Moderately Severe	50-59
Severe	35-49
Very Severe	< 35

(Pellegrino et al., 2005)

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

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

Epworth Sleepiness Scale (ESS): The ESS is an 8-item questionnaire which is used to determine the level of a person's daytime sleepiness. The ESS is based on 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 April 21, 2023).

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, 2014).

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

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

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

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

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, 2020).

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

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

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/m^2) and daytime hypercapnia (arterial PaCO2 > 45 mmHg) 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): 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/hr.

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 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 refer to RBD.

Periodic Limb Movement Disorder (PLMD): A sleep disorder characterized by periodic episodes of repetitive, highly stereotyped limb movements that occur during sleep, in conjunction with clinical sleep disturbance or fatigue that cannot be

accounted for by another primary sleep disorder or other etiology (ICSD-3, 2014).

Periodic Limb 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 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 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, irresistible urge to move the limbs. This urge to move is often, but not always, accompanied by other uncomfortable sensations felt deep inside the limbs or by a feeling that is difficult or impossible to describe. Although the legs are most prominently affected, these sensations may occur in the arms as well (ICSD-3, 2014).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by 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

CPT Code	Description
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

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

Description of Services

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

The evaluation of sleep disorders can be done at home or in a specialized sleep center that can study sleep patterns during the day or at night. Home Sleep Apnea Testing (HSAT) is used to diagnose OSA and records breathing rate, airflow, heart rate, and blood oxygen levels during sleep. These studies are performed at home without a sleep technician present (unattended). Polysomnography (PSG) records breathing, heart rate, blood oxygen levels, body movements, brain activity and eye movements during sleep. PSG is performed in a laboratory setting with a sleep technician present (attended) (American Thoracic Society, 2015; updated 2019).

Once a diagnosis of OSA is made, a PAP trial (titration) is sometimes 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; updated 2019).

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 and idiopathic

Hypersomnia. 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; updated 2019).

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 April 21, 2023)

Multiple-Night Home Sleep Apnea Testing Versus One-Night Home Sleep Apnea Testing

Results of clinical studies demonstrate that night-to-night variability in HSAT is comparable to laboratory-based PSG. The reported RDI variability is small and a single-night testing can correctly diagnose OSA in the majority of 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).

Clinical Evidence

In 2011, Collop et al. reported the results of a technology evaluation of sleep testing devices used in the OOC setting performed by an AASM task force. Only peer-reviewed English literature and devices measuring two 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, two 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 two piezoelectric or respiratory inductance plethysmographic (RIP) belts (but not one 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, refer to the full text article at:
https://aasm.org/resources/practiceparameters/outofcenter.pdf. (Accessed April 21, 2023)

Single-Night Versus Multiple-Night Home Sleep Apnea Testing

Results of the following clinical studies suggest that night-to-night variability in HSAT is comparable to laboratory-based PSG and that a single night testing can correctly diagnose OSA in the majority of patients with a high pretest-probability of OSA.

Levendowski et al. (2009) investigated the variability of AHI obtained by PSG and by in-home portable recording in 37 patients 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). Patients biased toward more time supine during the initial PSG. No trends in time supine for in-home studies were noted.

Night-to-night variability in HSAT was previously assessed in a number of clinical studies. Most of these studies involved a small number of patients. Redline et al. (1991), Quan et al. (2002; erratum 2009) and Davidson et al. (2003) found no evidence of a statistically significant difference in RDI between nights 1 and 2, suggesting that there was no significant respiratory first-night effect.

Fietze et al. (2004) investigated the night-to-night variability and diagnostic accuracy of the oxygen desaturation index (ODI) in 35 patients using the portable recording device MESAM-IV at home during seven 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 ≤ 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 one-night recordings.

A larger study by Stepnowsky et al. (2004) examined the nightly variability of AHI in a retrospective comparison of three sequential nights of testing performed in the home in 1,091 patients who were referred for diagnostic testing of sleep-disordered breathing (SDB). Based on night one, approximately 90% of patients were classified consistently with “AHI-high” (the highest AHI measured across the three nights) using an AHI threshold of five. However, 10% were misclassified on night one relative to the highest AHI level. The authors concluded that there is little, if any, significant nightly change in SDB in the home environment.

Home-Based Versus In-Laboratory Diagnostic and Therapeutic Pathway

Comparative effectiveness research studies have shown that clinical outcomes of patients 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 patients managed with in-laboratory PSG.

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. 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 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.

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 hour-AHI) and 3 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 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 ≥ 20 to 40) may be revised to a lower number, allowing for more efficient use of resources.

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 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.

Using a cohort study design, 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.

Results of a randomized controlled multicenter non inferiority study by Antic et al. (2009) compared nurse-led home diagnosis and CPAP therapy with physician-led current best practice in OSA management in 195 patients. There were no differences between both groups in ESS score and CPAP adherence at 3 months.

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.

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.

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).

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.

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 patients 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 patients 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 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 patients 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 patients 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)

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., 2018) 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 reflects 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).

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, 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 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 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.

Krahn et al. (2021) updated AASM's protocols for the administration of the MSLT and MWT. 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.

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:

- Among patients with a high pretest probability for OSA, we suggest a manually-scored type III HSAT (unattended portable monitor) using an event index (i.e., RDI, AHI) ≥ 15 events per hour to establish the diagnosis of moderate to severe OSA.
- For patients with a high pretest probability for OSA and a non-diagnostic HSAT (i.e., technically inadequate or AHI < 5), we recommend repeat (HSAT or lab-based PSG) testing for OSA.
  (Department of Veterans Affairs and Department of Defense, 2019)

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 regulated by the FDA as Class II Devices 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/pmn.cfm. (Accessed April 21, 2023)

The FDA has approved several HSAT devices 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/pmn.cfm. (Accessed April 21, 2023)

Actigraphy devices are classified as sleep assessment devices (product code LEL). Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 21, 2023)

References

American Academy of Sleep Medicine (AASM). AASM Style Guide for Sleep Medicine Terminology. Updated November 2015. Available at: https://aasm.org/download-free-aasm-style-guide-for-sleep-medicine-terminology/. Accessed April 21, 2023.

American Academy of Sleep Medicine (AASM). AASM Manual for the Scoring of Sleep and Associated Events: Rules, terminology and technical specifications. V3. February 2023.

American Academy of Sleep Medicine (AASM). International Classification of Sleep Disorders, 3rd ed. (ICSD-3) Darien, IL: American Academy of Sleep Medicine, 2014.

American Academy of Sleep Medicine (AASM). Standards for accreditation of out of center sleep testing (OCST) in adult patients. Available at: https://aasm.org/accreditation/. Accessed April 21, 2023.

American Thoracic Society. Patient Education/Information Series. Sleep studies: in the sleep laboratory and in the home. Am J Respir Crit Care Med. 2015 Aug 15;192(4):p3-4; online version updated October 2019.

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

Arand D, Bonnet M, Hurwitz T, et al. The clinical use of the MSLT and MWT. Sleep. 2005 Jan;28(1):123-44.

Aurora RN, Kristo DA, Bista SR, et al.; American Academy of Sleep Medicine. The treatment of restless legs syndrome and periodic limb movement disorder in adults – an update for 2012: practice parameters with an evidence-based systematic review and meta-analyses: an American Academy of Sleep Medicine Clinical Practice Guideline. Sleep. 2012 Aug 1;35(8):1039-62.

Aurora RN, Zak RS, Maganti RK, et al.; Standards of Practice Committee; American Academy of Sleep Medicine. Best practice guide for the treatment of REM sleep behavior disorder (RBD). J Clin Sleep Med. 2010 Feb 15;6(1):85-95. Erratum in: J Clin Sleep Med. 2010 Apr 15;6(2):table of contents.

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

Berry RB, Hill G, Thompson L, et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. Sleep. 2008 Oct 1; 31(10):1423-31.

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

Caples SM, Anderson WM, Calero K, et al. Use of polysomnography and home sleep apnea tests for the longitudinal management of obstructive sleep apnea in adults: an American Academy of Sleep Medicine clinical guidance statement. J Clin Sleep Med. 2021 Jun 1;17(6):1287-1293.

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

Collop NA, Anderson WM, Boehlecke B, et al.; Portable Monitoring Task Force of the American Academy of Sleep Medicine. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. J Clin Sleep Med. 2007 Dec 15;3(7):737-47.

Collop NA, Tracy SL, Kapur V, et al. Obstructive sleep apnea devices for out-of-center (OOC) testing. Technology Evaluation. J Clin Sleep Med. 2011 Oct 15;7(5):531-48.

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

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

DeMaria EJ, Murr M, Byrne TK, et al. Validation of the obesity surgery mortality risk score in a multicenter study proves it stratifies mortality risk in patients undergoing gastric bypass for morbid obesity. Ann Surg. 2007 Oct;246(4):578-82; discussion 583-4.

Department of Veterans Affairs and Department of Defense. VA/DoD Clinical Practice Guidelines. The management of chronic insomnia disorder and obstructive sleep apnea. October 2019. Available at: https://www.healthquality.va.gov/guidelines/CD/insomnia/VADoDSleepCPGFinal508.pdf. Accessed April 21, 2023.

Eckert DJ, Jordan AS, Merchia P, Malhotra A. Central sleep apnea: Pathophysiology and treatment. Chest. 2007 Feb;131(2):595-607.

Epstein LJ, Kristo D, Strollo PJ Jr, et al.; Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. J Clin Sleep Med. 2009 Jun 15; 5(3):263-76.

Fietze I, Dingli K, Diefenbach K, et al. Night-to-night variation of the oxygen desaturation index in sleep apnea syndrome. Eur Respir J 2004; 24:987-93.

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

Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management and prevention of chronic obstructive pulmonary disease. Updated 2023. Available at: https://goldcopd.org/2023-gold-report-2/. Accessed April 21, 2023.

Hening W, Allen R, Earley C, et al. The treatment of restless legs syndrome and periodic limb movement disorder. An American Academy of Sleep Medicine Review. Sleep. 1999 Nov 1;22(7):970-99.

Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017 Mar 15;13(3):479-504.

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

Krahn LE, Arand DL, Avidan AY, et al. Recommended protocols for the Multiple Sleep Latency Test and Maintenance of Wakefulness Test in adults: guidance from the American Academy of Sleep Medicine. J Clin Sleep Med. 2021 Dec 1;17(12):2489-2498.

Krakow B, Ulibarri V, Melendrez D, et al. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia patients with sleep disordered breathing to positive airway pressure (PAP-NAP). J Clin Sleep Med. 2008 Jun 15;4(3):212-22.

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

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

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

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

Littner MR, Kushida C, Wise M, et al.; Standards of Practice Committee of the American Academy of Sleep Medicine. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. Sleep 2005 Jan 1; 28(1):113-21.

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

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

New York Heart Association. Criteria Committee. Nomenclature and criteria for diagnosis of diseases of the heart and great vessels. 9th ed. Boston, MA: Little, Brown & Co.; 1994: 253-256.

Pellegrino R, Viegi G, Brusasco V, et al. Interpretative strategies for lung function tests. Eur Respir J. 2005 Nov;26(5):948-68.

Plante DT. Leg actigraphy to quantify periodic limb movements of sleep: a systematic review and meta-analysis. Sleep Med Rev. 2014 Oct;18(5):425-34.

Quan SF, Griswold ME, Iber C, et al. Sleep Heart Health Study (SHHS) Research Group. Short-term variability of respiration and sleep during unattended nonlaboratory polysomnography – the Sleep Heart Health Study. [corrected]. Sleep. 2002 Dec; 25(8):843-9. Erratum in: Sleep. 2009 Oct 1; 32(10): table of contents.

Redline, S, Tosteson, T, Boucher, MA, et al. Measurement of sleep-related breathing disturbances in epidemiologic studies: assessment of the validity and reproducibility of a portable monitoring device. Chest 1991;100,1281-1286.21st.

Rosen IM, Kirsch DB, Carden KA, et al.; American Academy of Sleep Medicine Board of Directors. Clinical use of a home sleep apnea test: an updated American Academy of Sleep Medicine Position Statement. J Clin Sleep Med. 2018 Dec 15;14(12):2075-2077.

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

Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. Sleep. 1999 Aug 1;22(5):667-89.

Smith MT, McCrae CS, Cheung J, et al. Use of actigraphy for the evaluation of sleep disorders and circadian rhythm sleep-wake disorders: an American Academy of Sleep Medicine Systematic Review, Meta-Analysis, and GRADE Assessment. J Clin Sleep Med. 2018a Jul 15;14(7):1209-1230.

Smith MT, McCrae CS, Cheung J, et al. Use of actigraphy for the evaluation of sleep disorders and circadian rhythm sleep-wake disorders: an American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2018b Jul 15;14(7):1231-1237.

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

Ulibarri VA, Krakow B, McIver ND. The PAP-NAP one decade later: patient risk factors, indications, and clinically relevant emotional and motivational influences on PAP use. Sleep Breath. 2020 Dec;24(4):1427-1440.

Yancy CW, Jessup M, Bozkurt B, et al.; American College of Cardiology Foundation; American Heart Association Task Force on Practice Guidelines. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Oct 15;62(16):e147-239.

Yancy CW, Jessup M, Bozkurt B, et al.; 2017 ACC/AHA/HFSA Focused update of the 2013 ACCF/AHA Guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. J Am Coll Cardiol. 2017 Aug 8;70(6):776-803.

Policy History/Revision Information

Date	Summary of Changes
01/01/2024	**Application** ***Kentucky and North Carolina*** • Updated reference link to reflect current title for state-specific policy version
11/01/2023	**Application** ***Ohio*** • Updated reference link to reflect current title for state-specific policy version
10/01/2023	**Title Change** • Previously titled *Attended Polysomnography for Evaluation of Sleep Disorders* **Application** • Reformatted content; modified language to indicate this Medical Policy does not apply to the following states: ○ Indiana ○ Kentucky ○ Louisiana ○ Nebraska ○ New Jersey ○ North Carolina ○ Ohio ○ Pennsylvania ○ Tennessee **Coverage Rationale** • Replaced reference to "attended full-channel *nocturnal* polysomnography sleep study" with "attended full-channel polysomnography sleep study" ***Daytime Sleep Studies*** • Revised language pertaining to medical necessity clinical coverage criteria for **Multiple Sleep Latency Testing (MSLT)**; added reference to the InterQual® CP: Procedures, Sleep Studies (Pediatric) • Replaced language indicating: ○ "Maintenance of Wakefulness Testing (MWT) is medically necessary for evaluating an *individual* who is unable to stay awake resulting in a safety issue or assessing response to treatment in *individuals* with sleep disorders" with "Maintenance of Wakefulness Testing (MWT) is medically necessary for evaluating an *adult* who is unable to stay awake resulting in a safety issue or assessing response to treatment in *adults* with sleep disorders" ○ "PAP Nap is not medically necessary" with "*abbreviated daytime sleep studies* (e.g., PAP-Nap) is not medically necessary" • Removed language indicating the following studies are not medically necessary due to insufficient evidence of efficacy: ○ MSLT for diagnosing OSA, Insomnia, or circadian rhythm disorders ○ MWT for diagnosing OSA, Insomnia, or circadian rhythm disorders ***Attended Repeat Testing*** • Replaced language indicating "repeat attended full-channel polysomnography, *performed in a health care facility or laboratory setting, as well as* repeat PAP titration, is medically necessary for certain individuals who have persistent or new symptoms, despite documented appropriate current treatment or PAP therapy" with "repeat attended full-channel polysomnography *and* repeat PAP

Date	Summary of Changes

	titration, is medically necessary for certain individuals who have persistent or new symptoms, despite documented appropriate current treatment or PAP therapy"
	Definitions
	• Removed definition of:
	  ○ Periodic Limb Movement Arousal Index (PLMAI)
	  ○ Periodic Limb Movement Index (PLMI)
	• Updated definition of:
	  ○ Apnea
	  ○ Respiratory Effort-Related Arousal (RERA)
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
	• Archived previous policy version CS098.Z

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies 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.