Sleep Studies, Adult

Humana

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Medical Coverage Policy

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Related Medical/Pharmacy Coverage Policies

Digital Therapeutics

Home Oximetry Monitoring

Obstructive Sleep Apnea and Other Sleep Related Breathing Disorders Nonsurgical Treatments Obstructive Sleep Apnea and Other Sleep Related Breathing Disorders Surgical Treatments

Description

A sleep study is a test that may be used to assist in the diagnosis of sleep disorders such as sleep apnea, narcolepsy or other nighttime behaviors. It can record a range of bodily functions during sleep such as:

- Brain, heart and muscle activity
- Eye movement
- Heart monitoring
- Oxygen saturation levels
- Respiratory effort, rate and rhythm

A sleep study may be performed in the home or in a sleep facility/laboratory.

Home Based Testing

Home/portable monitor sleep testing, or **home sleep apnea testing (HSAT)**, is a sleep study performed in the home that utilizes portable monitoring (PM) devices that are designed to be used by an individual without supervision of a sleep technologist and the results are evaluated by a qualified physician. The system usually consists of a recording device and related accessories. PM devices measure fewer parameters than a laboratory based sleep study. The American Academy of Sleep Medicine (AASM) has created categorization parameters of home sleep testing devices or what is more commonly referred to in literature, as the <u>Type I – IV Classification System</u>. Only those monitors that record airflow, respiratory effort and blood oxygenation (at a minimum) are considered effective for the evaluation of sleep apnea.

Examples of these devices include, but may not be limited to:

- AccuSom
- AcuPebble Ox100
- Alice PDx
- Apnea Risk Evaluation System (ARES) (eg, Model 610, 620)
- ApneaLink Air
- BresoDX1
- Embletta MPR Sleep Data Recording System
- NomadAir PMU810
- Nox T3/T3s
- Onera Sleep Test System (Onera STS)
- Sleep Profiler PSG2 (SP29)
- Stardust II Sleep Event Recorder

Some of these devices are available over-the-counter (OTC) without a prescription. One example of this type of device is **Wesper Lab**. This is a digital recording device, which consists of an abdominal patch, a thoracic patch and a mobile application (app). The single-use, wireless patches are designed to record sleep data. **(Refer to Coverage Limitations section)**

Peripheral artery tonometry (PAT) is a PM device (not classified as AASM Type I – IV) that includes proprietary technology to analyze respiration during sleep. PAT uses a sensor on an individual's fingertip to noninvasively measure arterial volume changes during sleep that indicate sympathetic nervous system activation and respiratory disturbances.¹⁷ Examples of these devices include, but may not be limited to, **NightOwl, NightOwl Mini, WatchPAT 300** or **WatchPAT ONE**. These devices are for single use, which eliminates the risk of exposure to pathogens that could occur from reusable devices.

Actigraphy is a technique for monitoring body movement during sleep to detect sleep disorders by using a portable device known as an actigraph, which is worn on the individual's wrist or ankle. The main uses of actigraphy are to objectively measure sleep-wake cycles in individuals and to complement self-reported sleep duration in an individual with a range of sleep disorders.³³ (Refer to Coverage Limitations section)

Prescreening devices or procedures supposedly predict pretest probability of obstructive sleep apnea (OSA) prior to seeking a sleep study. Examples of prescreening devices include, but may not be limited to, **SleepStrip II** and acoustic pharyngometry. The **Belun Ring BLR-100X** is another example of a prescreening

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device. This device is used in conjunction with an application that purportedly measures sleep score, sleep apnea risk, sleep efficiency, stress level, sleep stage, oxygen saturation and pulse rate. (Refer to Coverage Limitations section)

Facility-Based Testing

Polysomnogram (PSG) is a sleep study that is performed in a facility/laboratory setting and requires an overnight stay. PSG is designed to capture multiple sensory channels including blood pressure, brain waves, breathing patterns and heartbeat as an individual sleeps. It can also record eye and leg movements as well as muscle tension which can be useful in diagnosing parasomnias. A PSG performed at a facility will record a minimum of 12 channels which involves at least 22 wire attachments to the individual. Sensors that send electrical signals to a computer are placed on the chest, face, head and legs. This test is attended by a technologist and the results are evaluated by a qualified physician. A PSG may be performed in conjunction with a positive airway pressure (PAP) machine to determine the titration of oxygen flow.

Facility-based positive airway pressure (PAP) titration study is used to set the right level of PAP which can be administered as continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) once individual tolerance and optimal levels are determined by a sleep technologist. Facility-based titration is indicated for an individual who is not a candidate for auto-titrating CPAP due to diminished ventilation from disorders such as chronic obstructive pulmonary disease (COPD), heart failure or obesity hypoventilation syndrome (OHS).

Facility-based PAP titration may be performed in conjunction with a PSG as part of a **split night** study if the diagnosis of moderate or severe OSA can be made within the first two hours of recorded sleep and at least three hours of PAP titration, including the ability of PAP to eliminate respiratory events during both rapid eye movement (REM) sleep and non-REM sleep, is demonstrated. If this is not possible, a second night in the sleep center may be necessary for the CPAP titration study.

Facility-based, daytime, abbreviated, cardiorespiratory sleep studies (**PAP NAP testing**) use a therapeutic framework that includes mask and pressure desensitization, emotion focused therapy to overcome aversive emotional reactions, mental imagery to divert the individual's attention from mask or pressure sensations and physiological exposure to PAP therapy during a 100 minute nap period which is purported to enhance PAP therapy adherence. **(Refer to Coverage Limitations section)**

Multiple sleep latency test (MSLT) is a facility-based study that is used to measure levels of daytime sleepiness. During a routine MSLT, an individual is given 5 nap trials that are separated by 2 hour intervals; each trial consists of a 20-minute session in which the individual attempts to fall asleep. Onset of sleep and REM, along with heartbeat and chin movements are recorded. The test is typically performed on the night following a negative nocturnal PSG (where at least 6 hours of sleep were achieved and sleep apnea was not diagnosed) in order to rule out other sleep disorders as a cause of excessive daytime sleepiness. The results of the study are primarily used to confirm the suspected diagnosis of narcolepsy.

Maintenance of wakefulness test (MWT) is a facility-based study that is used to measure the ability to stay awake and alert. The procedure protocol involves 4 nap trials, each trial consisting of a 40 minute session in which an individual attempts to fall asleep. The test is routinely performed in the daytime immediately following a negative nocturnal PSG and evaluates the ability to stay awake for a defined period of time.

Results may be used to determine the efficacy of therapy for sleep disturbance disorders (such as narcolepsy) or to determine if the inability to stay awake is a public or personal safety concern.

Artificial intelligence (AI) is being explored for many clinical uses including sleep study and sleep apnea testing. Examples of AI software include, but may not be limited to, **EnsoSleep** and **SomnoMetry**. The software automatically scores sleep study results by analyzing PSG signals recorded during sleep studies. The **Sunrise** device consists of a wireless AI-powered sensor placed on an individual's chin that records mandibular (lower jaw) movement. The data is sent to a mobile app that interprets results. (Refer to Coverage Limitations section)

Coverage Determination

All criteria below apply only to individuals 18 years of age or older.

Home/Portable Monitor Sleep Testing

Humana members may be eligible under the Plan for a **home/portable monitor (PM) sleep testing** to confirm the suspected diagnosis of moderate to severe obstructive sleep apnea (OSA) when **ALL** of the following criteria are met:

- Excessive daytime sleepiness (EDS) and at least **ONE** of the following are present:
 - Epworth Sleepiness Scale (ESS) score of 10 or greater; OR
 - $\circ~$ Excessive sleepiness while driving; OR~
 - Loud/intense snoring; OR
 - Witnessed nocturnal apnea, choking and/or gasping; AND
- Absence of the following comorbid medical condition(s) that would reduce the accuracy of a home/PM sleep test:
 - Moderate to severe pulmonary disease including, but may not be limited to:
 - Chronic obstructive pulmonary disease (COPD) with an FEV1 (forced expiratory volume in one second) less than 60%, use of home oxygen or evidence of hypoventilation such as carbon dioxide (CO₂) level greater than or equal to 45 mm Hg; OR
 - Nocturnal or uncontrolled asthma; OR
 - Neuromuscular disease with associated pulmonary disease including, but may not be limited to: amyotrophic lateral sclerosis, multiple sclerosis, myotonic dystrophy, Parkinson's, previous stroke with residual respiratory effects, spina bifida or uncontrolled epilepsy; OR
 - Cardiac disease, including but may not be limited to: congestive heart failure (CHF) (<u>New York Heart</u> <u>Association class III or IV</u> or left ventricular ejection fraction [LVEF] less than 45%), pulmonary hypertension or uncontrolled cardiac arrhythmia; **AND**

- <u>Type II, Type III, Type IV</u> (device must measure a minimum of 3 channels that include heart rate, oxygen saturation and respiratory analysis) or PAT PM device is used; **AND**
- Individual or caregiver has appropriate cognitive function, dexterity and mobility to use equipment safely at home; **AND**
- Home sleep testing results must be evaluated by a qualified physician

Repeat Sleep Study – Home/Portable Monitor Sleep Testing

Humana members may be eligible under the Plan for a **repeat home/portable monitor (PM) sleep test** when the following criteria are met:

- Evaluation following adjustment of an oral appliance prescribed for the treatment of OSA; OR
- Evaluation following surgery for OSA; OR
- Reassessment of an individual with documented OSA after significant weight loss or gain (10% of body weight) with persistent OSA symptoms

Facility-Based Polysomnogram

Humana members may be eligible under the Plan for a **facility-based PSG** to confirm the suspected diagnosis of moderate to severe OSA when the following criteria are met:

- EDS and at least **ONE** of the following are present:
 - ESS score of 10 or greater; OR
 - Excessive sleepiness while driving; OR
 - Loud/intense snoring; OR
 - Witnessed nocturnal apnea, choking and/or gasping; AND
- Individual presents with **ANY** of the following:
 - Diagnostic testing prior to planned hypoglossal nerve stimulator (HGNS) implantation for an individual with a known diagnosis of OSA; OR
 - History of or clinical features associated with central sleep apnea (CSA) (including CSA with Cheyne-Stokes breathing pattern, CSA due to high-altitude periodic breathing or CSA due to regular use of a long-acting opioid medication or other respiratory depressant for at least 2 months duration); OR
 - History of or clinical features associated with narcolepsy (moderate to severe daytime sleepiness associated with cataplexy, hypnagogic hallucinations or sleep paralysis) when a MSLT is planned; **OR**

- History of or clinical features associated with obesity hypoventilation syndrome (OHS) (BMI greater than 30kg/m² with alveolar hypoventilation when awake [PaCO₂ greater than 45 mmHg] which cannot be attributed to other conditions such as hypothyroidism, neuromuscular weakness, pleural pathology, pulmonary disease or skeletal restriction); OR
- History of traumatic brain injury (TBI) with EDS (eg, post-traumatic hypersomnia, post-traumatic narcolepsy); **OR**
- Idiopathic central nervous system hypersomnia (presence of difficult morning awakening, constant somnolence, prolonged night sleep or sleep drunkenness) when a MSLT is planned; OR
- Individual (or caregiver) lacks cognitive function, dexterity or mobility to use PM equipment safely at home; OR
- Mission critical profession including, but may not be limited to: airline pilots, bus drivers, military personnel and truck drivers; OR
- Moderate to severe pulmonary disease including, but may not be limited to:
 - Chronic obstructive pulmonary disease (COPD) with an FEV1 less than 60%, use of home oxygen or evidence of hypoventilation such as CO₂ level greater than or equal to 45 mm Hg; OR
 - Nocturnal or uncontrolled asthma; OR
- Neuromuscular disease with associated pulmonary disease including, but may not be limited to: amyotrophic lateral sclerosis, multiple sclerosis, myotonic dystrophy, Parkinson's, previous stroke with residual respiratory effects, spina bifida or uncontrolled epilepsy; OR
- Parasomnias that are unusual or atypical because of the duration, frequency or time of the behavior including, but may not be limited to: confusional arousals, nocturnal seizures, psychogenic dissociative states and REM sleep behavior disorder; OR
- Paroxysmal arousals or other sleep disruptions thought to be seizure related; OR
- <u>Periodic limb movement disorder</u>* (involuntary, jerking movements of the legs during sleep causing EDS due to sleep fragmentation); **OR**
- Cardiac disease, including but may not be limited to: CHF (<u>New York Heart Association class III or IV</u> or LVEF less than 45%), pulmonary hypertension or uncontrolled cardiac arrhythmia

*Periodic limb movement disorder (PLMD) is NOT the same condition as restless legs syndrome (RLS). PLMD is a sleep disorder involving involuntary, repetitive movements of the limbs and may be related to diseases such as anemia, diabetes or kidney disease. RLS is a condition characterized by uncomfortable sensations in the legs which worsen at night and cause a compelling urge to move the legs.

Repeat Sleep Study – Facility-Based Polysomnogram

Humana members may be eligible under the Plan for a **repeat facility-based PSG** when the following criteria are met:

- Diagnostic testing prior to planned hypoglossal nerve stimulator (HGNS) implantation for an individual with a known diagnosis of OSA; **OR**
- Individual (or caregiver) lacks cognitive function, dexterity or mobility to use PM equipment safely at home; **OR**
- Reassessment warranted of an individual with documented OSA after significant weight loss or gain (10% of body weight) with persistent OSA symptoms; **OR**
- Results of previous home/PM sleep test or PAP device-generated data were indeterminate or technically inadequate for suspected OSA in an individual with a high pretest probability; **OR**
- Post-HGNS implantation for:
 - Titrating device parameters and determining therapeutic stimulation setting (approximately 1 month following the implantation); **OR**
 - Substantial weight gain (10% of body weight) with return of OSA symptoms

Facility-Based Positive Airway Pressure Titration Study

Humana members may be eligible under the Plan for **facility-based PAP titration study** when the following criteria are met:

• Conclusive diagnosis of OSA as documented by sleep study;

AND any of the following:

- Failure of APAP treatment trial; **OR**
- History of or clinical features associated with central sleep apnea (CSA) including CSA with Cheyne-Stokes breathing pattern, CSA due to high altitude periodic breathing or CSA due to regular use of a longacting opioid medication or other respiratory depressant for at least 2 months duration); **OR**
- History of or clinical features associated with OHS (BMI greater than 30kg/m² with alveolar hypoventilation when awake [PaCO₂ greater than 45 mmHg]), which cannot be attributed to other conditions such as hypothyroidism, neuromuscular weakness, pleural pathology, pulmonary disease or skeletal restriction; OR
- Individual (or caregiver) lacks cognitive function, dexterity and mobility to use PM equipment safely at home; **OR**

- Presence of comorbid medical condition(s) that would degrade the accuracy of home/portable monitor sleep testing when at least **ONE** of the following is present:
 - Moderate to severe pulmonary disease including, but may not be limited to: COPD, nocturnal or uncontrolled asthma; OR
 - Neuromuscular disease with associated pulmonary disease including, but may not be limited to: amyotrophic lateral sclerosis, multiple sclerosis, myotonic dystrophy, Parkinson's, previous stroke with residual respiratory effects, spina bifida or uncontrolled epilepsy; OR
 - Cardiac disease including, but may not be limited to: CHF (<u>New York Heart Association class III or IV</u> or LVEF less than 45%), pulmonary hypertension or uncontrolled cardiac arrhythmia; **OR**
 - Symptoms of OSA persist and/or attempts to comply with PAP device have failed despite documented provider support including proper fitting of device and individual education

Multiple Sleep Latency Test and Maintenance of Wakefulness Test

Humana members may be eligible under the Plan for **multiple sleep latency test (MSLT)** or **maintenance of wakefulness test (MWT)** when **ALL** of the following criteria are met:

- Assessment of treatment response or presence of associated features of narcolepsy such as: cataplexy, EDS/hypersomnia, hypnagogic hallucinations or sleep paralysis; **AND**
- Testing consists of nap opportunities performed at 2 hour intervals (initial nap opportunity begins within 90 minutes to 3 hours after termination of the nocturnal PSG recording); **AND**
- Testing is performed in the daytime immediately following a negative nocturnal PSG (during which a minimum of 6 hours sleep was achieved and sleep apnea not diagnosed) for the evaluation of symptoms of narcolepsy

Note: The criteria for **sleep studies** mentioned above are not consistent with the Medicare National Coverage Policy and therefore may not be applicable to Medicare members. Refer to the <u>CMS website</u> for additional information.

Coverage Limitations

Over-the-counter (OTC) items, whether prescribed or unprescribed are generally excluded by certificate. In the absence of a certificate exclusion, OTC items are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for a **facility-based polysomnogram (PSG)**, **facility-based PAP titration study** or **home/portable monitor (PM) sleep testing** for **ANY** indications other than those listed above, including the following:

- Circadian rhythm disorders; OR
- Common, uncomplicated or noninjurious parasomnias, such as typical disorders of arousal, bruxism, enuresis, nightmares or sleep talking; **OR**
- Facility-based or home sleep testing to calibrate or evaluate noncovered devices; OR
- Home sleep testing not evaluated by a qualified physician; OR
- Insomnia; OR
- Restless legs syndrome (RLS)

All other indications are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **MSLT or MWT** for any indications other than those listed above, including:

- Performance following a positive PSG (during which a minimum of 6 hours sleep was achieved and sleep apnea or OSA diagnosed); **OR**
- Single nap studies for the diagnosis of any sleep disorder, including narcolepsy; OR
- Unattended or home MSLT study

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for the following study/testing for any indication:

- Sleep study testing using artificial intelligence; OR
- Facility-based, daytime, abbreviated, cardiorespiratory sleep studies (PAP NAP testing) to acclimate individuals to PAP; **OR**
- Facility-based PAP titration study for upper airway resistance syndrome (UARS); OR
- Prescreening devices or procedures to predict pretest probability of OSA prior to seeking a sleep study;
 OR
- Stand-alone actigraphy for the diagnosis of any sleep disorder

This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time	
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)	
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)	Not Covered
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 (eg, thoracoabdominal movement)	
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist	Not Covered if used to report any sleep study outlined in Coverage Limitations section
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	

CPT[®] Category III Description **Comments** Code(s) No code(s) identified HCPCS Description **Comments** Code(s) Not Covered if used to report any device Durable medical equipment, miscellaneous E1399 outlined in Coverage Limitations section Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, G0398 ECG/heart rate, airflow, respiratory effort and oxygen saturation Home sleep test (HST) with type III portable monitor, G0399 unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation Home sleep test (HST) with type IV portable monitor, G0400 unattended; minimum of 3 channels

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Appendix

Appendix A

AASM Type I-IV Classification System for Monitoring ⁴⁹			
Type I Monitoring Devices	 Used for in laboratory, technologist attended, overnight polysomnogram (PSG). Measure a minimum of seven parameters including: airflow, chin electromyogram, electrocardiogram (ECG), electroencephalogram (EEG), electrooculogram, oxygen saturation and respiratory effort. 		
Type II Monitoring Devices	 Record a minimum of seven parameters, the same as Type I devices. Devices are portable, used outside the sleep lab and are unattended by a sleep technologist. 		
Type III Monitoring Devices	 Usually measure a minimum of four parameters, including two respiratory variables, such as respiratory movement and airflow, a cardiac parameter (eg, heart rate or ECG) and oxygen saturation through pulse oximetry. Some Type III devices may offer extra measurements, such as detection of snoring and movement. Devices are portable, used outside the sleep lab and are unattended by a sleep technologist. 		
Type IV Monitoring Devices	 Generally record only one or two parameters, usually measuring oxygen saturation or airflow. Some Type IV devices measure additional parameters but do not meet the definition of a Type III device. Devices are portable, used outside the sleep lab and are unattended by a sleep technologist. 		

Appendix B

New York Heart Association (NYHA) Functional Classification System⁴³

Classification	Symptoms
Class I	Individual with cardiac disease, but without resulting limitations on physical
(mild)	activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.
Class II	Individual with cardiac disease resulting in slight limitations on physical activity.
(mild)	They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
Class III (moderate)	Individual with cardiac disease resulting in marked limitations on physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
Class IV (severe)	Individual with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increases.

Appendix C Epworth Sleepiness Scale (ESS)⁵⁹

Situation	Score
Sitting and reading	
Watching TV	
Sitting inactive in public place	
Passenger in car	
Lying down to rest in afternoon	
Sitting talking to someone	
Sitting after lunch without alcohol	
In a car, stopped for minutes in traffic	
Total	

Dozing

- **0** = Never
- 1 = Slight Chance
- 2 = Moderate Chance
- **3** = High Chance

Respondents score each item from zero (would never doze) to three (high chance of dozing); responses are summed to generate a total score ranging from 0 to 24. ESS scores greater than 10 are considered abnormal and supportive of a complaint of EDS.

Change Summary

- 02/29/2024 Annual Review, No Coverage Change.