

Sleep Studies (for Ohio Only)

Policy Number: CS098OH.A

Effective Date: November 1, 2023

[Instructions for Use](#)

Table of Contents	Page
Application	1
Coverage Rationale	1
Definitions	2
Applicable Codes	3
Description of Services	3
Clinical Evidence	5
U.S. Food and Drug Administration	8
References	8
Policy History/Revision Information	9
Instructions for Use	11

Related Policies

- [Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements \(for Ohio Only\)](#)
- [Obstructive and Central Sleep Apnea Treatment \(for Ohio Only\)](#)

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Home Sleep Apnea Testing

For medically necessity clinical coverage criteria for Home Sleep Apnea Testing ([HSAT](#)) and home-based Autotitration Positive Airway Pressure (APAP), refer to the InterQual® CP: Procedures, Sleep Studies.

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

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

For medical necessity clinical coverage criteria for facility-based polysomnography, refer to the InterQual® CP: Procedures:

- Sleep Studies
- Sleep Studies (Pediatric)

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

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 \(for Ohio Only\)](#) for implantable hypoglossal nerve stimulator indications.

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

- 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.

For medical necessity clinical coverage criteria for multiple sleep latency testing (MSLT) and maintenance of wakefulness testing (MWT), refer to the InterQual® CP: Procedures:

- Sleep Studies
- Sleep Studies (Pediatric)

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

For medical necessity clinical coverage criteria for facility-based titration studies, split-night, or full night sleep studies, refer to the InterQual® CP: Procedures:

- Sleep Studies
- Sleep Studies (Pediatric)

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

Attended Repeat Testing

For medical necessity clinical coverage criteria for repeat attended full-channel polysomnography performed in a health care facility or laboratory setting, as well as repeat PAP titration, refer to the InterQual® CP: Procedures:

- Sleep Studies
- Sleep Studies (Pediatric)

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

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.

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).

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).

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.

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).

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).

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 Guidelines may apply.

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

CPT® is a registered trademark of the American Medical Association

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

Description of Services

Sleep disorders are conditions that affect an individual's normal sleep patterns and can have an impact on quality of life. One of the most common sleep disorders is Obstructive Sleep Apnea (OSA), a condition in which a person stops breathing during

sleep due to a narrowed or closed airway. Symptoms of OSA include daytime sleepiness, loud snoring, and breathing interruptions, or awakenings due to gasping or choking. If left untreated, OSA can lead to serious health consequences such as hypertension, heart disease, stroke, insulin resistance and obesity. Other sleep disorders include Central Sleep Apnea, periodic limb movement disorder (PLMD), narcolepsy, restless legs syndrome, parasomnias and insomnia.

The evaluation of sleep disorders can be done at home or in a specialized sleep center that can study sleep patterns during the day or at night. Home Sleep Apnea Testing (HSAT) is used to diagnose OSA and records breathing rate, airflow, heart rate and blood oxygen levels during sleep. These studies are performed at home without a sleep technician present (unattended). Polysomnography (PSG) records breathing, heart rate, blood oxygen levels, body movements, brain activity and eye movements during sleep. PSG is performed in a laboratory setting with a sleep technician present (attended) (American Thoracic Society, 2015; 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 2 or more bioparameters were included in the analysis. Studies evaluating 20 different devices or models (e.g., ARES, ApneaLink, Embletta, Novasom QSG/Bedbugg/Silent Night, SNAP, Stardust II, Watch-PAT) were reviewed. Devices were judged on whether or not they can produce a positive likelihood ratio (LR+) of at least 5 and a sensitivity of at least 0.825 at an in-lab AHI of at least 5. The authors concluded that:

- The literature is currently inadequate to state with confidence that a thermistor alone without any effort sensor is adequate to diagnose OSA
- If a thermal sensing device is used as the only measure of respiration, 2 effort belts are required as part of the montage and piezoelectric belts are acceptable in this context
- Nasal pressure can be an adequate measurement of respiration with no effort measure with the caveat that this may be device specific
- Nasal pressure may be used in combination with either 2 piezoelectric or respiratory inductance plethysmographic (RIP) belts (but not 1 piezoelectric belt);
- There is insufficient evidence to state that both nasal pressure and thermistor are required to adequately diagnose OSA
- With respect to alternative devices for diagnosing OSA, the data indicate that:
 - Peripheral arterial tonometry (PAT) devices are adequate for the proposed use;
 - The device based on cardiac signals shows promise, but more study is required as it has not been tested in the home setting
 - For the device based on end-tidal CO₂ (ETCO₂), it appears to be adequate for a hospital population; and for devices utilizing acoustic signals
 - The data are insufficient to determine whether the use of acoustic signals with other signals as a substitute for airflow is adequate to diagnose OSA

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

<https://aasm.org/resources/practiceparameters/outofcenter.pdf>. (Accessed April 21, 2023)

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

- AASM suggests that clinicians use actigraphy to estimate sleep parameters in adult patients with insomnia disorder. (Conditional)
- AASM suggests that clinicians use actigraphy in the assessment of pediatric patients with insomnia disorder. (Conditional)
- AASM suggests that clinicians use actigraphy in the assessment of adult patients with circadian rhythm sleep-wake disorder. (Conditional)

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

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

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

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

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/pmnmn.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/pmnmn.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/pmnmn.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 4, 2022.

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

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.

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.

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.

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.

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.

Ohio Administrative Code/5160/Chapter 5160-1-01. Medicaid medical necessity: definitions and principles. Available at: <https://codes.ohio.gov/ohio-administrative-code/rule-5160-1-01>. Accessed May 23, 2023.

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.

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*. 2018 Jul 15;14(7):1231-1237.

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.

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.

Policy History/Revision Information

Date	Summary of Changes
11/01/2023	<p>Application</p> <ul style="list-style-type: none">Added language to indicate any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01 <p>Coverage Rationale</p> <p>Home Sleep Apnea Testing</p> <ul style="list-style-type: none">Replaced coverage guidelines with instruction to refer to the InterQual® CP: Procedures, Sleep Studies for medical necessity clinical coverage criteria for Home Sleep Apnea Testing (HSAT) and home-based autotitration positive airway pressure (APAP) <p>Attended Full-Channel Polysomnography, Performed in a Healthcare Facility or Laboratory Setting</p> <ul style="list-style-type: none">Replaced references to “attended full-channel <i>nocturnal</i> polysomnography” with “attended full-channel polysomnography”

Date	Summary of Changes
	<ul style="list-style-type: none"> • Added language to indicate 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 <i>Obstructive and Central Sleep Apnea Treatment (for Ohio Only)</i> for implantable hypoglossal nerve stimulator indications • Removed language indicating: <ul style="list-style-type: none"> ○ Attended full-channel nocturnal polysomnography is medically necessary for evaluating individuals with suspected OSA [when criteria listed in the policy are met] ○ Attended full-channel nocturnal 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 [listed] conditions • Replaced medical necessity clinical coverage criteria with instruction to refer to the following guidelines for facility-based polysomnography: <ul style="list-style-type: none"> ○ InterQual® CP: Procedures, Sleep Studies ○ InterQual® CP: Procedures, Sleep Studies (Pediatric) • Revised list of studies that are not medically necessary; removed “attended full-channel polysomnography for evaluating circadian rhythm disorders, depression, or insomnia” <p>Daytime Sleep Studies</p> <ul style="list-style-type: none"> • Revised language to indicate: <ul style="list-style-type: none"> ○ Multiple sleep latency testing (MSLT) and maintenance of wakefulness testing (MWT) may be performed during the night if necessary to match an individual’s normal sleep pattern ○ For medical necessity clinical coverage criteria for multiple sleep latency testing (MSLT) and maintenance of wakefulness testing (MWT), refer to the InterQual® CP: Procedures: <ul style="list-style-type: none"> ▪ Sleep Studies ▪ Sleep Studies (Pediatric) ○ Abbreviated daytime sleep studies (e.g., PAP-Nap) are not medically necessary due to insufficient evidence of efficacy <p>Attended PAP Titration and Attended Repeat Testing</p> <ul style="list-style-type: none"> • Replaced medical necessity clinical coverage criteria with instruction to refer to the following guidelines for facility-based polysomnography, repeat attended full-channel polysomnography performed in a health care facility or laboratory setting, and repeat PAP titration: <ul style="list-style-type: none"> ○ InterQual® CP: Procedures, Sleep Studies ○ InterQual® CP: Procedures, Sleep Studies (Pediatric) <p>Definitions</p> <ul style="list-style-type: none"> • Updated definition of “Polysomnogram (Attended)” • Removed definition of: <ul style="list-style-type: none"> ○ Apnea ○ Apnea Hypopnea Index (AHI) ○ Central Disorders of Hypersomnolence ○ Chronic Pulmonary Disease (CPD) ○ Circadian Rhythm ○ Circadian Rhythm Sleep-Wake Disorders ○ Epworth Sleepiness Scale (ESS) ○ Excessive Sleepiness [Somnolence, Hypersomnia, Excessive Daytime Sleepiness (EDS)] ○ Hypersomnia (Excessive Sleepiness) ○ Hypersomnolence ○ Hypopnea ○ Insomnia ○ Maintenance of Wakefulness Test (MWT) ○ Medically Necessary ○ Monitoring Time ○ Multiple Sleep Latency Test (MSLT) ○ Narcolepsy ○ New York Heart Association (NYHA) Heart Failure Classification

Date	Summary of Changes
	<ul style="list-style-type: none"> ○ Obesity Hypoventilation Syndrome (OHS) ○ Obstructive Sleep Apnea (OSA) ○ Parasomnia ○ Periodic Limb Movement Arousal Index (PLMAI) ○ Periodic Limb Movement Disorder (PLMD) ○ Periodic Limb Movement Index (PLMI) ○ Periodic Limb Movements of Sleep (PLMS) ○ Positive Airway Pressure (PAP) ○ Rapid Eye Movement Sleep Behavior Disorder (RBD) ○ Respiratory Effort-Related Arousal (RERA) ○ Respiratory Event Index (REI) ○ Restless Legs Syndrome (RLS)/Willis-Ekbom Disease <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information ● Archived previous policy version CS098OH.U – P

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) 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 uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.