

MEDICAL POLICY	Sleep Disorder Testing (All Lines of Business Except Medicare)
Effective Date: 05/01/2021  <div style="text-align: right;">5/1/2021</div>	Medical Policy Number: 60 Medical Policy Committee Approved Date: 6/14; 10/14; 1/15; 4/15; 9/15; 3/16; 7/16; 9/17; 1/18; 2/18; 1/19; 12/19; 6/2020; 04/2021
Medical Officer Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Notes:

- This medical policy does not contain medical necessity criteria for home sleep testing, which may be considered medically necessary in patients suspected of having obstructive sleep apnea. Consecutive home sleep studies are considered a single test. Additional reimbursement will not be covered for consecutive home sleep study nights.
- This medical policy does not address home sleep testing or facility-based polysomnography in patients 17 years of age or younger, which may be considered medically necessary.
- See [definitions](#) section for terms used in the policy criteria.

Policy Criteria Links

- [Split-Night Study \(Facility-Based Polysomnography with Initiation of Positive Airway Pressure\)](#)
- Full-Night Facility Based Polysomnography:
 - [To Diagnose Sleep Related Disorders](#)
 - [For Risk Screening in Patients with Excessive Daytime Sleepiness](#)
 - [To Diagnose non-OSA Sleep Disorders](#)
- [Repeat Full-Night Facility-Based Polysomnography](#)
- [Facility-Based Polysomnography for Positive Airway Pressure Titration](#)
- [Multiple Sleep Latency Test \(MSLT\)](#)
- [Repeat MSLT Testing](#)
- [Non-Covered Testing](#)

Split-Night Study (Facility-Based Polysomnography with Initiation of Positive Airway Pressure)

- I. Facility-based polysomnography, in which the initial diagnostic portion of the PSG is followed by positive airway pressure (PAP) titration may be considered **medically necessary and covered** when **at least one** of the following (A.-C.) criteria are met:
 - A. The patient meets **all** of the following (1.-3.) criteria:
 1. The patient is experiencing **at least one** of the following (a.-c.) symptoms during sleep:
 - a. Snoring; **and/or**
 - b. Awakening with gasping or choking sensation; **and/or**
 - c. Witnessed apnea; **and/or**
 2. The patient is experiencing **at least one** of the following (a.-g.) additional symptoms or risk factors of sleep disordered breathing:
 - a. Excessive daytime sleepiness as characterized by **at least one** of the following (i.-iii.):
 - i. Questionnaires (Epworth Sleepiness Scale [ESS], Berlin, STOP BANG); **or**
 - ii. Sleepiness that interferes with activities of daily living (ADLs) and is not explained by other conditions; **or**
 - iii. Inappropriate daytime napping (e.g., while driving or eating); **and/or**
 - b. Fatigue; **and/or**
 - c. Irritability or moodiness; **and/or**
 - d. Morning headaches; **and/or**
 - e. Decreased concentration or memory loss; **and/or**
 - f. Increased neck circumference (> 17 inches in men or > 16 inches in women); **and/or**
 - g. Hypertension; **and**
 3. **At least one** of the following (a.-d.) sleep disorders is suspected:
 - a. Central sleep apnea or hypoventilation disorder; **or**
 - b. Obesity hypoventilation syndrome; **or**

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- c. Co-existing sleep disorder; **or**
 - d. Obstructive sleep apnea **and** the patient has **at least one** of the following (i.-vi.) comorbid conditions that would be expected to degrade the accuracy of a home/portable study:
 - i. Significant cardiorespiratory disease (e.g., chronic obstructive pulmonary disease [COPD], congestive heart failure New York Heart Association [NYHA] Class III or IV); **and/or**
 - ii. Potential respiratory muscle weakness due to neuromuscular conditions; **and/or**
 - iii. Awake hypoventilation or suspicion of sleep-related hypoventilations; **and/or**
 - iv. Chronic opioid medication use; **and/or**
 - v. History of stroke; **and/or**
 - vi. Severe insomnia; **or**
 - B. A single home sleep test was negative, inconclusive, or technically inadequate to establish a diagnosis of obstructive sleep apnea (OSA) in a patient with a high likelihood of OSA **and** criterion I.A.1. **and** I.A.2. above are met; **or**
 - C. The patient with a high likelihood of OSA **and** has impaired cognition or mobility, which might limit the ability to operate home testing equipment, **and** criterion I.A.1. **and** I.A.2. above are met.
- II. Facility-based polysomnography (PSG), in which the initial diagnostic portion of the PSG is followed by positive airway pressure (PAP) titration is considered **not medically necessary and is not covered** when criterion I. above is not met.

Full-Night Facility-Based Polysomnography to Diagnose Sleep Related Disorders

- III. A full-night of facility-based polysomnography may be considered **medically necessary and covered** for the diagnosis of suspected sleep disorders when clinical documentation indicates a split-night study is not clinically appropriate **and at least one** of the following (A.-C.) criteria are met:
- A. The patient meets **all** of the following (1.-3.) criteria:
 - 1. The patient is experiencing **at least one** of the following (a.-c.) symptoms during sleep:
 - a. Snoring; **and/or**
 - b. Awakening with gasping or choking sensation; **and/or**
 - c. Witnessed apnea; **and/or**
 - 2. The patient is experiencing **at least one** of the following (a.-g.) additional symptoms or risk factors of sleep disordered breathing:
 - a. Excessive daytime sleepiness as characterized by **at least one** of the following (i.-iii.):
 - i. Questionnaires (Epworth Sleepiness Scale [ESS], Berlin, STOP BANG); **or**
 - ii. Sleepiness that interferes with activities of daily living (ADLs) and is not explained by other conditions; **or**

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- iii. Inappropriate daytime napping (e.g., while driving or eating); **and/or**
- b. Fatigue; **and/or**
- c. Irritability or moodiness; **and/or**
- d. Morning headaches; **and/or**
- e. Decreased concentration or memory loss; **and/or**
- f. Increased neck circumference (> 17 inches in men or > 16 inches in women); **and/or**
- g. Hypertension; **and**
- 3. **At least one** of the following (a.-d.) sleep disorders is suspected:
 - a. Central sleep apnea or hypoventilation disorder; **or**
 - b. Obesity hypoventilation syndrome; **or**
 - c. Co-existing sleep disorder; **or**
 - d. Obstructive sleep apnea **and** the patient has **at least one** of the following (i.-vi.) comorbid conditions that would be expected to degrade the accuracy of a home/portable study:
 - i. Significant cardiorespiratory disease (e.g., chronic obstructive pulmonary disease [COPD], congestive heart failure New York Heart Association (NYHA) Class III or IV); **and/or**
 - ii. Potential respiratory muscle weakness due to neuromuscular conditions; **and/or**
 - iii. Awake hypoventilation or suspicion of sleep-related hypoventilations; **and/or**
 - iv. Chronic opioid medication use; **and/or**
 - v. History of stroke; **and/or**
 - vi. Severe insomnia; **or**
- B. A single home sleep test was negative, inconclusive, or technically inadequate to establish a diagnosis of obstructive sleep apnea (OSA) in a patient with a high likelihood of OSA **and** criterion III.A.1. **and** III.A.2. above are met.; **or**
- C. The patient with a high likelihood of OSA **and** has impaired cognition or mobility, which might limit the ability to operate home testing equipment, **and** criterion III.A.1. **and** III.A.2. above are met.

Full-Night Facility-Based Polysomnography for Risk Screening in Patients with Excessive Daytime Sleepiness

- IV. A full-night of facility-based polysomnography in patients who are experiencing unexplained excessive daytime sleepiness (defined as an Epworth sleepiness scale [ESS] score of 10 or greater) may be considered **medically necessary and covered** when **all** of the following (A.-F.) criteria are met:
 - A. The patient's safety or job performance is compromised; **and**
 - B. Medical conditions considered and treated if indicated; **and**
 - C. No psychiatric disorder by history or psychiatric disorder managed; **and**
 - D. Medications deemed noncontributory; **and**
 - E. Drug or alcohol misuse excluded; **and**

- F. **At least one** of the following (1.-4.) sleep disorders is suspected:
1. Central sleep apnea or hypoventilation disorder; **or**
 2. Obesity hypoventilation syndrome; **or**
 3. Co-existing sleep disorder; **or**
 4. Obstructive sleep apnea.

Full-Night Facility-Based Polysomnography for non-OSA Sleep Disorders

- V. A full night of facility-based polysomnography may be considered **medically necessary and covered** when a comorbid sleep-related disorder other than obstructive sleep apnea is suspected. These may include, but are not limited to, hypersomnia, narcolepsy, parasomnia, and periodic limb movement disorder.

Repeat Full-Night Facility-Based Polysomnography

- VI. Repeat facility-based polysomnography may be considered **medically necessary and covered** when **at least one** of the following (A.-D.) criteria are met:
- A. To post-operatively assess the efficacy of an obstructive sleep apnea (OSA) surgical treatment (e.g. Uvulopalatopharyngoplasty [UPPP]); **or**
 - B. The patient has undergone surgical treatment for OSA or adhered to a prescribed non-surgical treatment (e.g., oral appliance or positive airway pressure [PAP]) and has worsening or recurrent symptoms; **or**
 - C. In OSA patients for the assessment of treatment results on PAP therapy after substantial weight loss (e.g., 10% of body weight); **or**
 - D. To assess OSA patients on PAP therapy after substantial weight gain (10% of body weight) who also experience a return of symptoms.
- VII. Repeat facility-based polysomnography is considered **not medically necessary and not covered** when criterion X. above is not met.

Facility-Based Polysomnography for Positive Airway Pressure Titration

- VIII. Facility-based polysomnography for positive airway pressure (PAP) titration following a previous diagnostic study may be considered **medically necessary and covered** when **at least one** of the following (A.-D.) criteria is met:
- A. The patient has a confirmed diagnosis of **at least one** of the following (1.-4.) sleep disorders:
 1. Central sleep apnea or hypoventilation disorder; **or**
 2. Obesity hypoventilation syndrome; **or**
 3. Co-existing sleep disorder; **or**

- 4. Obstructive sleep apnea **and** the patient has **at least one** of the following (a.-f.) comorbid conditions that would be expected to degrade the accuracy of a home/auto titration:
 - a. Significant cardiorespiratory disease (e.g., chronic obstructive pulmonary disease [COPD], congestive heart failure New York Heart Association (NYHA) Class III or IV); **and/or**
 - b. Potential respiratory muscle weakness due to neuromuscular conditions; **and/or**
 - c. Awake hypoventilation or suspicion of sleep-related hypoventilations; **and/or**
 - d. Chronic opioid medication use; **and/or**
 - e. History of stroke; **and/or**
 - f. Severe insomnia; **or**
 - B. The patient has failed or is contraindicated for an auto positive airway pressure (APAP) treatment trial; **or**
 - C. The patient has failed a continuous positive airway pressure (CPAP) trial and needs bilevel positive airway pressure (BiPAP) or adaptive servo ventilation (ASV) titration; **or**
 - D. The patient has impaired cognition or mobility, which might limit the ability to operate home/auto titration equipment.
- IX. Facility-based polysomnography for positive airway pressure (PAP) titration is considered **not medically necessary and is not covered** when criterion XII. above is not met.

Multiple Sleep Latency Test (MSLT)

- X. Multiple sleep latency testing (MSLT) may be considered **medically necessary and covered** when either of the following criteria is met (A.-B.):
 - A. When used as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis, and is completed in conjunction with polysomnography conducted no more than 24 hours prior to MSLT; **or**
 - B. When used as part of the evaluation of patients with suspected idiopathic hypersomnia to help differentiate idiopathic hypersomnia from narcolepsy.
- XI. Multiple sleep latency testing (MSLT) is considered **not medically necessary and is not covered** when criterion X. above is not met.

Repeat MSLT Testing

- XII. Repeat MSLT testing may be considered **medically necessary and covered** when any of the criteria are met (A.-C.):
 - A. The initial test was affected by extraneous circumstances; **or**
 - B. Appropriate study conditions were not present during initial testing; **or**
 - C. When the patient is suspected to have narcolepsy but earlier MSLT evaluation(s) did not provide polygraphic confirmation.

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XIII. Repeat MSLT testing is considered **not medically necessary and is not covered** when criterion XII. above is not met.

Non-Covered Testing

XIV. Actigraphy testing (i.e., ActiGraph, Actiware, ActiTrac, Actiwatch) for the diagnosis of sleep-related disorders is considered **investigational and is not covered**.

XV. Sleep studies using devices that do not provide a measurement of apnea-hypopnea index (AHI) and oxygen saturation are considered **not medically necessary and are not covered** for any indication.

XVI. Remote-controlled titration of an oral appliance (e.g. the MATRx oral appliance titration study) (CPT: 95999) is considered **not medically necessary and not covered**.

Link to [Policy Summary](#)

POLICY GUIDELINES

Definitions

- Apnea: the cessation of airflow for at least 10 seconds
- Hypopnea: abnormally slow or shallow breathing resulting in reduced airflow
- Apnea-hypopnea index (AHI): the number of apnea and hypopnea events per hour of sleep; used to indicate the severity of sleep apnea
- Respiratory disturbance index (RDI): the number of apnea and hypopnea events per hour of sleep plus the number of respiratory-effort related arousals (RERAs) per hour of sleep
- Respiratory-effort related arousals (RERAs): an abnormal breathing event which does not meet the criteria for an apnea or hypopnea, but is an arousal of sleep associated with a respiratory event noted during a sleep study
- Mild sleep apnea: AHI or RDI score of 5 to 14 and is typically associated with involuntary daytime sleepiness during activities that require little attention such as reading or watching television.
- Moderate sleep apnea: AHI or RDI score of 15 to 30 associated with involuntary sleepiness during activities that require moderate attention such as meetings or presentations.
- Severe sleep apnea: AHI or RDI score of greater than 30 and is typified by daytime sleepiness during activities that require active attention such as driving or talking. The score may exceed 100 in patients with very severe OSA.
- Epworth Sleepiness Scale (ESS): a self-administered questionnaire that asks respondents to rate their usual chances of dozing off or falling asleep while engaged in different activities
- Excessive daytime sleepiness: a score of > 10 on the ESS
- Cataplexy: Cataplexy is a sudden and uncontrollable muscle weakness or paralysis that comes on during the day and is often triggered by a strong emotion, such as excitement or laughter.
- Sleep paralysis: the temporary inability to move or speak while falling asleep or upon waking

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- Hypnagogic hallucinations: a vivid dreamlike hallucination that occurs as one is falling asleep
- Severe insomnia: a nightly complaint of an insufficient amount of sleep or not feeling rested after the habitual sleep episode. It is accompanied by severe impairment of social or occupational functioning. Severe insomnia is associated with feelings of restlessness, irritability, anxiety, daytime fatigue, and tiredness.
- Coexisting Sleep Disorder: a variety of disorders including, but not limited to, sleep onset insomnia, sleep maintenance insomnia, circadian rhythm sleep disorder, or restless leg syndrome
- 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

BILLING GUIDELINES

Initial prior authorization approval is for either 95810 or 95811. Any additional sleep disorder testing requires submission of a new prior authorization.

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
Facility-Based Polysomnography	
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
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
No Prior Authorization Required	
Home Sleep Studies	
Note: Consecutive home sleep studies are considered a single test. Additional reimbursement will not be covered for consecutive home sleep study nights.	
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

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G0400	Home sleep test (hst) with type iv portable monitor, unattended; minimum of 3 channels
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)
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
Not Covered	
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered.	
95999	Unlisted neurological or neuromuscular diagnostic procedure

DESCRIPTION

Sleep Disorders

Obstructive Sleep Apnea (OSA)

OSA is a sleep disorder in which a person stops breathing during sleep due to an obstruction of the upper airway. This obstruction is due to inadequate motor tone of the tongue and/or airway dilator muscles. Signs and symptoms of OSA include witnessed apneas, snoring, daytime sleepiness, obesity, and large neck circumference. OSA has become increasingly recognized as an independent risk factor for cardiac, neurologic, and perioperative morbidities.

Central Sleep Apnea (CSA)

In contrast to OSA where ongoing respiratory efforts are observed, CSA is defined by a lack of respiratory effort during the cessation of airflow. This results in insufficient or absent ventilation and compromised gas exchange during sleep. CSA is associated with frequent nighttime awakenings, excessive daytime sleepiness, and increased risk for adverse cardiovascular outcomes. There are several manifestations of CSA, including idiopathic CSA (CSA of unclear etiology), narcotic-induced central apnea, high altitude periodic breathing, and Cheyne-Stokes breathing (breathing pattern characterized by changes in tidal volume and apneas).

Obesity Hypoventilation Syndrome (OHS)

OHS is a type of CSA that is typically defined as a combination of obesity (body mass index > 30 kg/m2) and arterial hypercapnia (Paco2 >45 mm Hg) during wakefulness not explained by other known causes

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of hypoventilation. Symptoms may be similar to those of OSA, including morning headaches and excessive daytime sleepiness.

Idiopathic Hypersomnia

Idiopathic hypersomnia is a chronic neurological disorder marked by an insatiable need to sleep that is not eased by a full night's slumber.¹ Similar to other hard-to-diagnose sleep disorders, prevalence estimates are difficult to come by. As the name "idiopathic" hypersomnia implies, the pathophysiology of IH is presently unknown. These patients take frequent, unrefreshing naps, have difficulty waking up, and experience sleep drunkenness (post-awakening confusion). Idiopathic Hypersomnia Diagnostic Criteria, International Classification of Sleep Disorders, third edition states that all of the following criteria must be met:

1. Daily daytime sleepiness, defined as an "irrepressible need to sleep" or daytime sleep, that has been present at least 3 months
2. No cataplexy
3. No MSLT evidence for narcolepsy (i.e., fewer than two sleep onset REM periods on the overnight PSG and daytime MSLT considered together)
4. Electrophysiologic evidence of hypersomnolence, defined as either (or both) of:
 - a) Mean sleep latency on MSLT of ≤ 8 minutes
 - b) At least 11 hours of sleep per 24 hours, documented on a single 24 hour PSG or averaged across at least seven days of actigraphic monitoring during ad lib sleep
5. Insufficient sleep is ruled out (including immediately prior to 24 hour PSG, if performed)
6. No other disorder or substance use better explains the symptoms

Abbreviations: MSLT = multiple sleep latency test; REM = rapid eye movement; PSG = polysomnogram

Narcolepsy

There are two types of narcolepsy, according to the International Classification of Sleep Disorders, Third Edition² (ICSD-3): narcolepsy type 1 (NT1) and type 2 (NT2).² Narcolepsy is relatively rare. NT1 affects between 20 and 67 people per 100,000 in the United States. NT1 is two to three times more common than NT2 (estimated to affect about 20 people per 100,000).

NT1 is associated with the symptom of cataplexy, which is the sudden loss of muscle tone. NT1 was formerly known as "narcolepsy with cataplexy." NT2 was formerly known as "narcolepsy without cataplexy." People with NT2 have many similar symptoms as people with NT1, but they do not have cataplexy or low levels of hypocretin-1. If a person with NT2 later develops cataplexy or low hypocretin-1 levels, their diagnosis can be reclassified as NT1. This change in diagnosis is estimated to occur in about 10% of cases.

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Parasomnia

“Parasomnia” is a catchall term for unusual behaviors that people experience prior to falling asleep, while asleep, or during the arousal period between sleep and wakefulness. These behaviors vary considerably in terms of characteristics, severity, and frequency.³ Parasomnias were historically believed to be a definitive sign of psychopathology, though modern research suggests that these phenomena occur as the brain transitions in and out of sleep, and perhaps between rapid eye movement (REM) and non-rapid eye movement (NREM) sleep cycles. Each type of parasomnia has specific diagnostic criteria, though they are grouped into three generalized categories: NREM-related, REM-related, and “other.”

Periodic Limb Movement Disorder (PLMD)

Periodic limb movement disorder (PLMD) is a rare sleep disorder characterized by periodic, repetitive movements of the legs and feet during sleep (arms are sometimes also affected).⁴ Approximately 4 to 11 percent of the population is affected by PLMD. PLMD can be a primary or secondary disorder, and in the case of primary PLMD, scientists still do not know what causes the condition. Two potential causes are dopamine deficiency or miscommunication between nerves along the spinal cord. While PLMD can co-occur with other sleep disorders, it most frequently occurs with restless leg syndrome (RLS). Between 80 to 90 percent of people with RLS also have PLMD.

Sleep Disorder Testing

Home or Facility-based Polysomnography (PSG)

Table 1. Delineation of operational rules used to classify monitors in sleep studies⁵

Type	Portability	Number of Channels	Indicative Signals	≥ 2 airflow/effort channels	Identifies sleep/wake	Measures AHI
Type I	Facility-based	~14-16	<ul style="list-style-type: none"> • Electroencephalogram (EEG) • Electrooculogram (EOG) • Electromyography (EMG) • Electrocardiogram (ECG) or heart rate • Air flow • Respiratory effort • Oxygen saturation 	Yes	Yes	Yes
Type II	Portable	≥7	<ul style="list-style-type: none"> • Electroencephalogram (EEG) • Electrooculogram (EOG) 	Yes	Yes	Yes

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			<ul style="list-style-type: none"> • Chin electromyography (EMG) • Electrocardiogram (ECG) or heart rate • Air flow • Respiratory effort • Oxygen saturation 			
Type III	Portable	≥4	<ul style="list-style-type: none"> • Two respiratory variables (e.g., respiratory movement and airflow) • Cardiac variable (e.g., electrocardiogram [ECG] or heart rate) • Oxygen saturation 	Yes	No	No
Type IV	Portable	~1-2	<ul style="list-style-type: none"> • All monitors not qualifying for Type III 	No	No	No

Positive Airway Pressure Titration

Positive airway pressure (PAP) devices are used to treat patients with sleep related breathing disorders, including obstructive sleep apnea.⁶ Following polysomnography (PSG) and a diagnosis of sleep apnea, PAP titration is performed to determine the optimal pressure for maintaining upper airway patency. “Continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BPAP) represent the two forms of PAP that are manually titrated during PSG to determine the single fixed pressure of CPAP or the fixed inspiratory and expiratory positive airway pressures (IPAP and EPAP, respectively) of BPAP for subsequent nightly usage.”

Split-Night Polysomnography

In split-night polysomnography, a patient undergoes routine in-lab polysomnography and if a diagnosis of sleep apnea is established, positive airway pressure (PAP) titration commences thereafter.⁷ This allows for both the diagnosis and optimal levels of PAP therapy to be achieved in one night; therefore eliminating the need for an additional night of titration following polysomnography.

Multiple Sleep Latency Test (MSLT)

According to the American Academy of Sleep Medicine, “(t)he multiple sleep latency test (MSLT) is a diagnostic tool that measures the time it takes an individual to fall asleep in ideal quiet conditions during the day.⁸ It objectively measures daytime sleepiness. Colloquially known as the daytime nap study, MSLT is also a standard tool used to diagnose idiopathic hypersomnia and narcolepsy.” This diagnostic test takes a full day to complete, and it includes four to five 20 minute naps throughout the day. The test measures the length of time it takes for one to fall asleep, as well as brain waves, muscle activity, and

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eye movements. Based on this, a score is calculated which classifies one as manageable, troublesome, or severe sleepiness.

Actigraphy

Actigraphy involves wearing a device during sleep to record movements that can be used to estimate sleep parameters with specialized algorithms in computer software.⁹ Most commonly, the device is worn on the wrist, similar to a watch. The device may be worn for several weeks and evaluates sleep patterns and circadian rhythms. The purported benefit of actigraphy is the ability to diagnose excessive daytime sleepiness, insomnia, circadian rhythm sleep disorders, and/or restless legs syndrome in a less-cumbersome manner.

Titration of an Oral Appliance

Oral appliance therapy is a first-line treatment modality for varying severities of obstructive sleep apnea. Appliances are custom fabricated by specially trained dentists, and must be fitted for sleep time wear. The final fitting of the oral appliance may include an overnight sleep study to adjust the mandibular advancement device very slowly, i.e., titrating the device, with the aim to move the lower jaw so as to enlarge the upper airway and prevent collapse during sleep.¹⁰ The process of titration may be performed by a remotely controlled mandibular positioner (RCMP) during a full-night polysomnography (PSG). MATRx plus™ (Zephyry Sleep Technologies, Calgary, CA) is defined by the U.S. Food & Drug Administration (FDA) as an auto titration device for oral appliances (DEN170090).¹¹ Generally, these devices are:¹²

A closed-loop autotitration device for intraoral appliances uses a feedback control to record changes in the patient’s respiratory status related to repositioning of the mandible during an overnight study. The data are analyzed by a Healthcare Provider and can then be used to prospectively identify patients with mild to moderate obstructive sleep apnea who may be suitable for therapy with an oral appliance and to recommend a target mandibular position. MATRx Plus is a remote-controlled mandibular titration that is added to in-lab polysomnogram, which purports to improve the efficacy of oral appliances by determining the maximal therapeutic level of mandibular protrusion during sleep.

FDA Classification Product Code: QCJ

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of sleep disorder testing for the diagnosis of sleep related disorders. Below is a summary of the available evidence identified through February 2021. Due to the abundance of applicable literature, the evidence search was limited to systematic reviews and U.S. evidence-based clinical practice guidelines.

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In-Lab and Home Sleep Testing

In 2011, the Agency for Healthcare Research and Quality (AHRQ) conducted a systematic review of the evidence to evaluate the diagnosis and treatment of obstructive sleep apnea (OSA) in adults.⁵ Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. The key questions focused on OSA screening and diagnosis, treatments, associations between apnea-hypopnea index (AHI) and clinical outcomes, and predictors of treatment compliance. For the specific evaluation of the diagnosis of sleep apnea, the authors aimed to evaluate the comparative effectiveness of different diagnostic methods for sleep apnea.

The authors identified 15 quality A, 45 quality B, and 39 quality C studies evaluating Type III and Type IV monitors for OSA. This overall body of evidence was determined to be of moderate quality and suggested that “Type III and Type IV monitors may have the ability to accurately predict AHI suggestive of OSA with a high positive likelihood ratios and low negative likelihood ratios for various AHI cutoffs in PSG (polysomnography).” Overall, Type III monitors perform better than Type IV monitors at AHI cutoffs of 5, 10, 15 events/hour. The authors also state that “large differences compared with in-lab PSG cannot be excluded for all portable monitors” because the analyses suggest there may be substantial difference between PSG and Type III and Type IV monitors. The AHRQ evidence review identified no recent studies comparing Type II monitors with PSG. The authors cited a previous AHRQ technology assessment which concluded that “—based on [three quality B studies], type II monitors [used at home] may identify AHI suggestive of OSA with high positive likelihood ratios and low negative likelihood ratios, though —substantial differences in the [measurement of] AHI may be encountered between type II monitors and facility-based PSG.”

This AHRQ systematic review was of very good quality and had several strengths, including:

1. the gathering of evidence, assessment of quality, and extraction of data by several independent reviewers
2. contacting authors of selected studies for additional information or data
3. assessment of heterogeneity and publication bias
4. meta-analyses only being conducted when studies were determined to be homogeneous with respect to population, treatment, and outcome measures
5. sensitivity analyses to evaluate the influence of studies with a high risk of bias or high losses to follow-up

Limitations of this systematic review are seen in the inclusion of studies with a high risk of bias. Ultimately the authors concluded that portable monitors accurately predict OSA, but it is unclear whether they can replace laboratory-based PSG. The authors stated further “assessments with clinical outcomes are necessary to prove their value over polysomnography.”

Actigraphy

No systematic review or randomized controlled trials were identified for the use of actigraphy to diagnose sleep disorders. At least one review with meta-analyses has evaluated the technical validity of

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these devices by comparing to PSG.¹³ Though the authors found the device may be able to provide the consumer market with a gross estimate of sleep data, they are limited in specificity and not a substitute for PSG.

Several nonrandomized studies were also identified.¹⁴⁻¹⁸ Due to significant methodological limitations reliable conclusions cannot be drawn. Further studies of good methodological quality are required to support the clinical validity, clinical utility, and medical necessity of actigraphy for the diagnosis of sleep disorders.

Titration of an Oral Appliance

Several recent studies have assessed the clinical validity of remote-controlled oral appliance titration (i.e., MATRx), reporting that the device successfully identifies favorable candidates for oral appliance therapy, and accurately predicts effective target protrusive positions and treatment outcomes.¹⁹⁻²² Nonetheless, no data on long-term outcomes, impact on health outcomes and clinical utility has been published to date.

CLINICAL PRACTICE GUIDELINES

American Academy of Sleep Medicine (AASM)

- The 2018 AASM evidence-based clinical practice guideline for the use of actigraphy for the evaluation of sleep disorders and circadian rhythm sleep-wake disorders and gave the following recommendations:²³
 1. We suggest that clinicians use actigraphy to estimate sleep parameters in adult patients with insomnia disorder. (Conditional)
 2. We suggest that clinicians use actigraphy in the assessment of pediatric patients with insomnia disorder. (Conditional)
 3. We suggest that clinicians use actigraphy in the assessment of adult patients with circadian rhythm sleep-wake disorder. (Conditional)
 4. We suggest that clinicians use actigraphy in the assessment of pediatric patients with circadian rhythm sleep-wake disorder. (Conditional)
 5. We suggest 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)
 6. We suggest 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).
 7. We suggest that clinicians use actigraphy to estimate total sleep time in adult patients with suspected insufficient sleep syndrome. (Conditional)
 8. We recommend that clinicians *not* use actigraphy in place of electromyography for the diagnosis of periodic limb movement disorder in adult and pediatric patients (Strong).

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- The 2017 AASM evidence-based clinical practice guideline for the diagnostic testing for adult obstructive sleep apnea (OSA) gave the following recommendations:²⁴

“The following recommendations are intended as a guide for clinicians diagnosing OSA in adults. Under GRADE, 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.

Good Practice Statements:

- Diagnostic testing for OSA should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up.
- Polysomnography 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:

1. We recommend that clinical tools, questionnaires and prediction algorithms not be used to diagnose OSA in adults, in the absence of polysomnography or home sleep apnea testing. (STRONG)
2. We recommend that polysomnography, or home sleep apnea testing 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)
3. We recommend that if a single home sleep apnea test is negative, inconclusive, or technically inadequate, polysomnography be performed for the diagnosis of OSA. (STRONG)
4. We recommend that polysomnography, rather than home sleep apnea testing, 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)
5. We suggest that, if clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for polysomnography be used for the diagnosis of OSA. (WEAK)
6. We suggest that when the initial polysomnogram is negative and clinical suspicion for OSA remains, a second polysomnogram be considered for the diagnosis of OSA. (WEAK).”

- The 2005 AASM evidence-based practice parameters for the clinical use of the multiple sleep latency test (MSLT) gave the following recommendations:⁸

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- “The MSLT is indicated as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis. (Standard)
- The MSLT may be indicated as part of the evaluation of patients with suspected idiopathic hypersomnia to help differentiate idiopathic hypersomnia from narcolepsy. (Option)
- The MSLT is not routinely indicated in the initial evaluation and diagnosis of obstructive sleep apnea syndrome or in assessment of change following treatment with nasal CPAP.
- The MSLT is not routinely indicated for evaluation of sleepiness in medical and neurological disorders (other than narcolepsy), insomnia, or circadian rhythm disorders (Option)
- 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. (Standard)”

Because mean sleep latency is influenced by quantity of prior sleep, sleep fragmentation, and clinical sleep disorders, investigators also stated that “polysomnography must be performed immediately before the MSLT during the patient’s usual major sleep period as determined by the sleep clinician.”

American College of Physicians (ACP)

The 2014 ACP evidence-based clinical practice guideline for the diagnosis of obstructive sleep apnea in adults gave the following recommendations:²⁵

- ACP recommends a sleep study for patients with unexplained daytime sleepiness (Grade: weak recommendation, low-quality evidence).
- ACP recommends polysomnography (PSG) for diagnostic testing in patients with suspected obstructive sleep apnea (OSA). ACP recommends portable sleep monitors in patients without serious comorbidities as an alternative to PSG when PSG is not available for diagnostic testing. (Grade: weak recommendation, moderate-quality evidence).

Oregon Health Authority Health Evidence Review Commission (HERC)

The 2014 HERC evidence-based coverage guidance for the treatment of sleep apnea in adults stated the following:²⁶

“The following diagnostic tests for Obstructive Sleep Apnea (OSA) should be covered for adults:

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

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indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

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

POLICY SUMMARY

Facility-based polysomnography (PSG) has been widely accepted as the gold standard diagnostic test for sleep disorders. Home sleep testing (HST) is also an accurate diagnostic for ruling in obstructive sleep apnea; however, it is not indicated for patients with significant comorbid medical conditions (e.g., pulmonary disease, heart failure) which may degrade the accuracy of the portable testing. Therefore, facility-based polysomnography is indicated in these patients. The American Academy of Sleep Medicine (AASM) recommends the use of HST or facility-based PSG for the diagnosis of OSA. The AASM also states that if a single HST is negative, inconclusive, or technically inadequate, facility-based PSG be performed for the diagnosis of OSA. Split-night studies, when clinically appropriate, are also recommended by AASM. The AASM states follow-up PSG is indicated to evaluate the efficacy of certain OSA treatments, to evaluate recurring or worsening symptoms, or to assess patients on PAP therapy with significant weight loss or weight gain with a return of OSA symptoms.

The evidence is insufficient to establish the effectiveness of actigraphy for the diagnosis of OSA. Further studies of good methodological quality (e.g., randomized controlled trials) are required to establish the clinical utility and validity of actigraphy. The AASM states that actigraphy alone is not indicated for the routine diagnosis of OSA, but may be 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). Evidence is also insufficient to demonstrate the efficacy, long-term outcomes, impact on health outcomes and clinical utility of single-night oral appliance titration (e.g. MATRx).

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

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REGULATORY STATUS

U.S. Food and Drug Administration (FDA)

Home Sleep Testing Devices

The FDA has approved several home sleep testing devices under the 510(k) premarket notification process. Information regarding specific devices can be found by searching the FDA's 510(k) database for product code MNR.²⁷

In-Lab Polysomnography Devices

The FDA has approved several devices to record and analyze polysomnography data under the 510(k) premarket notification process. Information regarding specific devices can be found by searching the FDA's 510(k) database for product code GWQ.²⁸

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

- Sleep Disorder Testing (All Lines of Business Except Medicare)
- Sleep Disorder Testing (Medicare Only)
- Sleep Disorder Treatment: Positive Airway Pressure (All Lines of Business Except Medicare)
- Sleep Disorder Treatment: Positive Airway Pressure (Medicare Only)
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