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The Department of Vermont Health Access Clinical Criteria

Subject: Facility-Based Sleep Study/Polysomnogram AND Unattended/Home Sleep Apnea Test

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*Please note: Most current content changes will be highlighted in yellow.

Description of Service or Procedure

A sleep study involves the continuous and simultaneous monitoring and recording of various parameters and stages of sleep for a total of 6 or more hours. It requires a physician review, interpretation and a report.

A facility based sleep study is performed in a sleep laboratory, hospital, or other dedicated unit and is supervised by a sleep technologist. Sleep studies record neurophysiologic and cardiorespiratory data points. The data points are read by a trained technologist and interpreted by a sleep physician after the test has been completed. The test is used to diagnose sleep apnea and to determine its severity.

Unattended sleep studies are utilized as an alternative diagnostic test for the diagnosis of known or suspected obstructive sleep apnea (OSA). Per the American Association for Sleep Medicine (AASM) Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea (2017), unattended sleep studies are an alternative to a facility-based sleep study for uncomplicated individuals and is performed in the home. Per the AASM 2017 Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea, uncomplicated patients are those that are absent conditions that may indicate an increased risk of non-obstructive sleep-disordered breathing, absent concern for other significant non-respiratory sleep disorders, and absent other factors (personal or environmental) that would impact study data acquisition and in turn interpretation (see coverage criteria below for attended facility-based studies).

Unattended sleep study test results are equivalent to facility-based sleep study for diagnosis, treatment, and outcomes for uncomplicated individuals with signs and symptoms that indicate an increased risk of moderate to severe OSA. The data points are read by a trained technologist and interpreted by a sleep physician after the test has been completed. The test is used to diagnose sleep apnea and to determine its severity.

OSA is a potentially serious sleep disorder in which breathing repeatedly stops and starts during sleep. Several types of sleep apnea exist, but the most common type is obstructive sleep apnea, which occurs



when your throat muscles intermittently relax and block your airway during sleep creating snorting/gasping or choking sounds.

Apnea is the cessation or near cessation of respiration for a minimum of 10 seconds.

Apnea-hypopnea index (AHI) is the number of apneas or hypopneas recorded during the study per hour of sleep. It is generally expressed as the number of events per hour. Based on the AHI, the severity of OSA is classified either, mild, moderate, or severe. OSA is associated with observed apneas, excessive daytime sleepiness, or sleepiness that interferes with daily activities, or habitual snoring, gasping or chocking episodes associated with awakenings.

Sometimes the Respiratory Disturbance Index (RDI) is used which can be confusing because the RDI includes not only apneas and hypopneas, but may also include other, subtler, breathing irregularities. This means a person's RDI can be higher than his or her AHI.

The following AHI levels are used for the diagnosis of OSA:

Mild OSA: AHI ≥5, but <15
 Moderate OSA: AHI ≥ 15≤30

• Severe OSA: AHI \geq 30

Multiple Sleep Latency Testing (MSLT) is a tool used to assess daytime functioning as an index of the adequacy of sleep. MSLT is indicated as part of the evaluation of patients with suspected narcolepsy and may be useful in the evaluation of patients with suspected idiopathic hypersomnia. MSLT involves repeated measurement of sleep latency (time to onset of sleep) under standardized conditions during a day following quantified nocturnal sleep. The use of MSLT to support a diagnosis of narcolepsy is suspect if Total Sleep Time on the prior night sleep is less than 6 hours.

MSLT is usually preceded by an overnight sleep study and is helpful in identifying any additional sleep disorders (for example, sleep apnea or periodic limb movements in sleep) that could contribute to poor quality sleep. The MSLT should not be performed after a split-night sleep study.

Consider unattended sleep study for members unable to be studied in the sleep laboratory when such a study is not possible due to immobility, safety, or critical illness. Also, when initiation of treatment is urgent and standard polysomnography is not readily available.

Unattended Sleep testing performed for the diagnosis of obstructive sleep apnea must adhere to the guidelines specified in "Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients" (*Journal of Clinical Sleep Medicine*, Vol. 3, No. 7, 2007).

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at https://humanservices.vermont.gov/rules-policies/health-care-administrative-rules-hcar/adopted-rules

- 7102.2 Prior Authorization Determination
- 4.101 Medical Necessity for Covered Services
- 4.104 Medicaid Non-Covered Services

Coverage Position

Sleep Study may be covered for members:

- When the device is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont's Office of Professional Regulation's website*, who is knowledgeable in sleep medicine and who provides medical care to the member AND
- Unattended sleep study is covered only for the diagnostic study of OSA and for no other indications AND
- When the clinical guidelines below are met.

Coverage Criteria

Prior to testing there must be an order from the physician and a face-to-face (or telehealth) clinical evaluation by the treating or referred physician prior to the sleep test.

PA is required for a facility-based study.

PA is not required for an unattended sleep study/ home sleep apnea test.

PA **is not** required for pediatric members who are less than 18 years of age and the provider follows the Pediatric Guidelines set forth by the American Academy of Sleep Medicine.

Care should be integrated into a comprehensive program of patient evaluation and treatment outlined by The American Academy of Sleep Medicine: Standards for Accreditation. This should include appropriate health care utilization, comprehensive diagnostic assessment, accurate data collection and scoring and effective patient management.

A physician or other appropriately trained and supervised health provider is responsible for discussing the results of the test and recommendations with the patient.

Sleep study data can be manually scored by a Registered Polysomnographic Technologist (RPSGT) Sleep Technologist and validated and reported by a board-certified sleep specialist.

Unattended or Home Sleep Apnea Test (HSAT) may be considered medically necessary for adult patients who have symptoms suggestive of obstructive sleep apnea (OSA), when ALL of the following: (please review criteria for a facility study, as it may be a more appropriate procedure)

^{*} Vermont's Office of Professional Regulation's website: https://sos.vermont.gov/opr/

- 1. Moderate to severe probability of OSA
- 2. Member is 18 years or older
- 3. Caregiver/companion must be physically and cognitively capable of operating home testing equipment or the member is capable of operating home testing equipment.
- 4. Individual and/or companion should be educated in the correct application of sensors.
- 5. Absence of health conditions that decrease accuracy of the study. (See Facility-based criteria).
- 6. Limited to 1 night per testing episode.
- 7. Limited mobility, safety or critical illness
- 8. When initiation of treatment is urgent and standard polysomnography is not readily available. This must be noted in the clinical documentation
- 9. Approved devices for unattended sleep study include a minimum of measuring oxygen saturation, respiratory movement, airflow, and heart rate with at least 4 recording channels.
- 10. Auto-titrating CPAP machine shall be used to determine appropriate positive airway pressure parameters in lieu of a facility-based titration study.
- 11. Home Sleep studies are only covered for the diagnosis of Obstructive Sleep Apnea. They are not covered for any other sleep disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders or narcolepsy) or for screening asymptomatic persons. It is not appropriate for members with significant co-morbid medical conditions.

CPAP auto-titration has been introduced as an unattended method to determine optimal CPAP settings. Auto-titrating devices provide continuous self-adjustment and recording of CPAP requirements during a single overnight session or nightly for a period of several days to weeks. CPAP auto-titration is typically used after documentation and grading of OSA by either Attended or Unattended Sleep Study. A combination of Unattended Sleep Study and CPAP auto-titration can be used to accomplish both OSA diagnosis and CPAP titration in the home.

Attended facility-based sleep study may be considered **medically necessary** for patients who have symptoms suggestive of obstructive sleep apnea and other sleep disorders, when ANY of the following criteria are met:

- Moderate to severe pulmonary disease, neuromuscular disease, heart failure (see below for specifics), cognitive impairment, or impaired dexterity or mobility. Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy.
- COPD categories B, C, or D that is supported by clinical documentation of the following drugs but not limited to: (please note trade names may change)
 - A. **Corticosteroids:** such as prednisone, budesonide/formoterol (Symbicort), Fluticasone/salmeterol (Advair), fluticasone/vilanterol (Breo Ellipta)
 - B. **Anticholinergics:** such as Tiotropium (Spiriva), Ipratropium (Atrovent), Ipratropium-Albuterol (Combivent or Duo-Neb), aclidinium (Tudorza Pressair), Umeclidinium and Vilanterol (Anoro Ellipta),
 - C. Long-acting Beta 2 -agonists: such as Formoterol or Salmeterol
- History of stroke (greater than 30 days previously), ischemic transient attack, coronary artery disease, or sustained supraventricular tachycardia or bradycardia arrhythmias.
- Unexplained hypertension: systemic hypertension is common in patients with OSA. Sleep related apneas are associated with pronounced hemodynamic changes. OSA causes pulmonary hypertension and can contribute to sleep apnea. Hypertension is associated with cardiovascular

- morbidity and there is increasing evidence that there is a significant relationship between resistant hypertension and OSA.
- Uncontrolled congestive heart failure (CHF) Class III and IV. Class III is defined as marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea. Class IV is defined as unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.
- Disruptive Sleep Behaviors can occur during arousals from REM sleep or partial arousals from non-REM sleep. These parasomnias include nightmares, night terrors, sleepwalking, confusional arousals, restless leg syndrome (RLS) and periodic limb movement disorder (PLMD).
- If there is significant nocturnal oxygen desaturation during a HSAT defined as: Oxygen saturation is <= 88% for a total of 15 minutes or more of sleep time; or <90% for a total of 30 minutes or more of sleep time (excluding artifact) on a HSAT.
- Central sleep apnea.
- Obesity hypoventilation
- Suspected Narcolepsy: this test will provide evidence of sleepiness and to examine the pattern of REM sleep. This may help identify other disorders that may contribute to a patient's symptoms.
- Co-existing sleep disorder such as OSA and narcolepsy, idiopathic hypersomnia, periodic limb movement disorder, or parasomnias.
- Severe obesity:
 - A. BMI greater than 40; or
 - B. BMI > 35 with elevated PCO2 > 45 or
 - C. BMI > 35 plus the inability to lie flat due to difficulty with breathing.
- When Bi-level (BiPAP) or Adaptive Servo Ventilation PAP are specifically requested
- Member with prescribed supplemental oxygen for use in the home
- Suspected Nocturnal Seizures.
- History of Traumatic Brain Injury
- Chronic Opioid Treatment
- Insomnia
- Previous uvulopalatopharyngoplasty (UPPP) surgery to assess efficacy of surgery.
- Pregnancy > than 20 weeks
- Transcutaneous or End Tidal CO2 monitoring
- Individual and/or companion is incapable of operating home testing equipment.
- If the member is not capable of operating home testing equipment secondary to cognitive issues; please submit the clinical diagnosis that supports competency.
- Non-diagnostic or suboptimal Home Sleep Apnea Test
- Progressive neuromuscular disease/neurodegenerative disorder (examples include, but are not limited to, Parkinson's disease, myotonic dystrophy, amyotrophic lateral sclerosis, multiple sclerosis with associated pulmonary disease
- Multiple Sleep Latency Testing (MSLT) is medically necessary when it is indicated by all of the following:
 - A. Suspected narcolepsy; and

- B. Other causes of excessive sleepiness have been excluded by appropriate clinical assessment such as cataplexy, hypnagogic or hypnopompic, sleep paralysis and idiopathic hypersomnia.
- Preoperative or perioperative management for bariatric surgery
- Oral appliance/device check to assess efficacy
- Reevaluate the diagnosis of OSA and need for continued CPAP with weight loss of 10% body weight
- Follow-up PSG or HSAT can be used to reassess patients with recurrent or persistent symptoms, despite good PAP adherence.
- Testing for Post Hypoglossal Nerve Stimulation (HGNS) Implantation
 - A. Polysomnography at one-month post-implantation for the purpose of titrating the device parameters and determining therapeutic stimulation settings.
 - B. Following a titration study at one month. Clinical response is insufficient despite regular treatment with hypoglossal nerve stimulator and post a titration or substantial weight gain with return of symptoms.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence-based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

Follow-up Facility-Based Sleep Studies may be considered medically necessary to assess efficacy of oral appliances/devices. Follow-up facility or home sleep tests may be necessary to re-evaluate the diagnosis of OSA and need for continued positive airway pressure (CPAP), e.g., if there is a significant change in BMI (>10%) or the patient has undergone upper airway surgery or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued. Repeat study may be considered for members being treated for OSA who develop or have a change in cardiovascular disease or when residual AHI remains elevated, and the member is symptomatic.

For home sleep tests a second night of testing is allowed if technical difficulties occurred during the first study.

Coding guidelines

When a facility-based diagnostic sleep study and a facility-based sleep study with initiation of PAP therapy is requested only one unit will be approved. Example: 95810 and 95811 are requested. Both codes will be included on the prior authorization, but only one (1) unit will be approved. The language will read: Approve request for a facility-based diagnostic sleep study or sleep study with initiation of pap therapy (split-night) if criteria is met.

Type of service or procedure not covered (this list may not be all inclusive)

Unattended Sleep Study is considered **investigational** in children (younger than 18 years of age) and is therefore not covered by VT Medicaid. If a member's clinical situation requires a HSAT for this age group, a prior authorization will be required.

Actigraphy testing is a non-covered service.

Unattended Sleep Study is not appropriate for general screening of asymptomatic populations.

The DVHA does not cover and will not approve sleep studies, attended or unattended, solely for employment purposes unless clinical criteria has been met for suspicion of OSA.

Sleep Studies are not covered for chronic lung disease, circadian rhythm disorders, depression, or seizures in the absence of symptoms of sleep disorder.

Definitions

Apnea - cessation or near cessation of respiration for a minimum of 10 seconds.

Apnea - Hypopnea Index - the average number of episodes of apnea and hypopnea per hour without the use of a positive airway pressure device; also referred to as the respiratory disturbance index.

Cataplexy - a condition in which there are abrupt attacks of muscular weakness and hypotonia triggered by an emotional stimulus such as mirth, anger, fear or surprise.

Hypersomnolence - need for excessive amounts of sleep and sleepiness when awake.

Hypnagogic Hallucinations - vivid dream-like experiences at the time of falling asleep which the patient cannot distinguish from reality.

Hypoglossal Nerve Stimulation (HGNS) Implantation - a second-line therapy for those patients who have failed PAP therapy. It utilizes neuromodulation via an implantable stimulatory device. The system consists of a sensor to detect alterations in the breathing pattern, with a lead that stimulates the hypoglossal nerve to activate the genioglossus muscle and thus opens the pharyngeal airway. The stimulator is battery-powered, and the system is controlled by a patch, either wearable or remote.

Hypopnea - an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.

Insomnia - the complaint of inadequate sleep. Insomnia is subdivided into difficulty falling asleep, frequent or sustained awakenings, early morning awakenings, or persistent sleepiness despite sleep of adequate duration.

Parasomnia - a behavior disorder during sleep that is associated with brief or partial arousals but not with marked sleep disruption or impaired daytime alertness.

Periodic Limb Movement Disorder - also known as myoclonus and is characterized by involuntary, stereotypic, repetitive limb movements that may occur during sleep and usually involve the legs. This may cause frequent arousals and leads to insomnia or excessive daytime sleepiness. PLMD is not always associated with arousals or awakenings. It is most common in individuals over the age of 65. Not everyone who has PLMD has RLS, but 80% of people who have RLS also have PLMD. Causes are: hereditary, iron deficiency, Central Nervous System problems, kidney disorders, and may be an indicator of diabetes, kidney disease, and/or anemia. Diagnosis is usually from patient reported symptoms and from the sleep study that measures occurrences and scored to determine severity. Treatment may be: dopamine agonists, benzodiazepines, improved sleep hygiene, yoga, medication, and/or hot bath prior to bed.

REM Sleep Behavior Disorder - a rare parasomnia that primarily afflicts men of middle age or older, many of whom have a history of prior neurological disease. Presenting symptoms are of violent behavior during sleep reported by a bed partner. In contrast to sleepwalking, injury to patient or bystander is common, and upon awakening, the patient reports vivid, often unpleasant dream imagery.

Respiratory-Arousal Index - the total number of arousals per hour of sleep from apneas, hypopneas, and periodic increases in respiratory effort. Respiratory arousals may occur in the absence of sleep apneas or hypopneas but in association with snoring due to increased upper airway resistance, a condition called upper airway resistance syndrome (UARS).

Respiratory Disturbance Index (RDI) - the number of apneas, hypopneas and respiratory event related arousals (RERAs) per hour of sleep. The apnea-hypopnea index (AHI) is the number of apneas and hypopneas 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.

Restless Leg Syndrome - a neurologic disorder characterized by disagreeable leg sensations that usually occur at rest or before sleep and are alleviated by motor activity. Patients with this dyssomnia report an irresistible urge to move their legs when awake and inactive, especially when lying in bed just prior to sleep. This interferes with the ability to fall asleep. They report a creeping or crawling sensation deep within the calves or thighs, or sometimes even in the upper limbs, that is only relieved briefly by movement, particularly walking. Nearly all patients with restless legs also experience periodic limb movement disorder during sleep, although the reverse is not the case. Primary causes cannot be found and it is usually hereditary. Secondary causes by another disease or condition or side effect of certain medications such as: iron deficiency (with or without anemia), kidney failure, diabetes, Parkinson's disease, peripheral neuropathy, rheumatoid arthritis, pregnancy and SSRI's. RLS can be diagnosed from patient reports of symptoms and a facility-based sleep study and the use of the RLS rating scale.

Sleep Bruxism - an involuntary, forceful, grinding of the teeth during sleep that affects 10-20 percent of the population. The patient is usually aware of the problem with a typical age of onset at 17-20 years of age with spontaneous remission usually occurring by age 40.

Sleep Enuresis - bedwetting. Before age five or six, nocturnal enuresis should probably be considered a normal feature of development. The condition usually spontaneously improves at puberty, has prevalence in late adolescence of one to three percent, and is rare in adulthood.

Sleep Paralysis - the experience of being awake but unable to move that usually occurs near sleep onset or offset and lasts a few seconds.

Sleep Terrors - a disorder primarily occurring in children that is characterized by the child's sudden

screaming and exhibition of autonomic arousal with sweating, tachycardia and hyperventilation. The individual may be difficult to arouse and rarely remembers the episode on awakening in the morning.

Snoring - a rough, rattling, inspiratory noise produced by vibration of the pendulous palate, or sometimes of the vocal cords, during sleep or coma.

Somnambulism - sleepwalking that is usually characterized by the carrying out of automatic motor activities that range from minor to complex.

Somniloquy - the act of talking during sleep or in a hypnotic condition.

Upper Airway Resistance Syndrome (UARS) - a type of sleep apnea in which the patient demonstrates heavy snoring (stridor) without true hypopnea/apnea episodes.

Wakefulness Test - measurement of the ability to stay awake while the patient sits up in a dimly lit room (also referred to as Maintenance of Wakefulness Test (MWT) or Actigraphy. This is not currently a DVHA covered service.

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