The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required for CPAP, BiPAP, and intraoral appliances for Medicare Advantage. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. OSA is typically diagnosed by overnight monitoring with polysomnography (PSG). Medical management of OSA may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous positive airway pressure during sleep.

Background

In patients with OSA, the normal pharyngeal narrowing is accentuated by anatomic factors, such as a short, wide neck, elongated palate and uvula, or large tonsillar pillars with redundant lateral pharyngeal wall mucosa. Furthermore, OSA may be associated with a wide variety of craniofacial abnormalities, including micrognathia, retrognathia, or maxillary hypoplasia. In addition, OSA is associated with obesity. Obstruction anywhere along the upper airway can result in apnea. Therefore, OSA is associated with a heterogeneous group of anatomic variants producing obstruction.

The hallmark symptom of OSA is excessive daytime sleepiness; the hallmark clinical sign is snoring. The snoring abruptly ceases during the apnic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. Sleep fragmentation associated with repeated arousal during sleep can lead to impairment of daytime activity. For example, adult patients with OSA-associated daytime somnolence are thought to be at higher risk for accidents involving motorized vehicles, i.e., cars, trucks, or heavy equipment. OSA in children may result in neurocognitive impairment and behavioral problems. In addition, OSA affects the cardiovascular and pulmonary systems. For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This in turn can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile accidents related to daytime sleepiness.

Upper airway resistance syndrome (UARS) is a variant of OSA that is characterized by a partial collapse of the airway, resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha electroencephalographic (EEG) arousals (“respiratory event-related arousals” [RERAs]). The resistance to airflow is typically subtle and does not result in scoreable apneic or hypopneic events. RERAs are scored if there is a sequence of breaths lasting at least 10 seconds characterized by increasing respiratory effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea or hypopnea. Snoring may not be
a feature of UARS. However, it does result in increasingly negative intrathoracic pressure during inspiration, which can be measured using an esophageal manometer as an adjunct to a polysomnogram. Therefore, this diagnosis rests on polysomnographic documentation of greater than 10 EEG arousals per hour of sleep correlated with episodes of greater than normal negative intrathoracic pressures. RERAs can also be detected absent manometry during PSG. It has been proposed that UARS is a distinct syndrome from OSA that may be considered a disease of arousal. In the absence of intrathoracic pressure monitoring, a positive response to continuous positive airway pressure (CPAP) has also been used to support the diagnosis.

In adults, OSA is often suspected on the basis of the clinical history and physical appearance; i.e., an overweight individual with a wide neck. The most common symptoms are snoring, excessive daytime sleepiness, and hypertension. Excessive daytime sleepiness may be subjective and may be assessed by questionnaires such as the Epworth Sleepiness Scale (ESS), a short self-administered questionnaire that asks patients, “How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?”

1. Sitting and reading
2. Watching TV
3. Sitting inactive in a public place, i.e., theater
4. As a passenger in a car for one hour without a break
5. Lying down to rest in the afternoon when circumstances permit
6. Sitting and talking with someone
7. Sitting quietly after lunch without alcohol
8. In a car, while stopped for a few minutes in traffic

The patient rates his or her likelihood of falling asleep in these eight different situations as: 0 (would never doze), 1 (slight chance of dozing), 2 (moderate chance of dozing), or 3 (high chance of dozing). The maximum score is 24, and a score of 10 or below is considered normal.

Daytime sleepiness may also be measured objectively with tests such as the multiple sleep latency test or the maintenance of wakefulness test. The multiple sleep latency test measures how quickly the patient falls asleep when instructed to relax in a quiet and dimly lit room, and the maintenance of wakefulness test measures sleep latency when the patient is instructed to attempt to remain awake in an unstimulating environment. These tests are not considered necessary to evaluate sleep apnea, but the multiple sleep latency test may be used when symptoms, including excessive daytime sleepiness, suggest narcolepsy.

Daytime sleepiness is uncommon in young children with OSA. Symptoms in children may include habitual snoring (often with intermittent pauses, snorts, or gasps), disturbed sleep, and daytime neurobehavioral problems. OSA can occur in children of all ages, from neonates to adolescents. Risk factors include adenotonsillar hypertrophy, obesity, craniofacial anomalies, and neuromuscular disorders. In otherwise healthy children, OSA is usually associated with adenotonsillar hypertrophy and/or obesity. The first-line treatment for pediatric OSA is adenotonsillectomy.

The final diagnosis of OSA rests on a combination of clinical evaluation and objective criteria to identify those levels of obstruction that are considered to be clinically significant. The gold standard diagnostic test for sleep disorders is considered a polysomnogram, performed in a sleep laboratory. (1) A standard polysomnogram, supervised by a sleep lab technician, typically includes:

- EEG [electroencephalography] (to stage sleep, detect arousal)
- Submental electromyogram
• Electro-oculogram (to detect arousal, rapid eye movement [REM] sleep)

Additional parameters of sleep that are typically measured during in-lab PSG include:
• Respiratory airflow and effort (to detect apnea)
• Oxygen desaturation
• Electrocardiography
• Sleep position
• Leg movement
• Chest and abdominal excursions
• Continuous blood pressure monitoring
• Snoring

The first three elements listed here (EEG, submental electromyogram, electro-oculogram) are required for sleep staging. By definition, a polysomnogram always includes sleep staging, while a cardiorespiratory “sleep study” does not. The actual components of the study will be dictated by the clinical situation. Supervision of the test may be considered important to ensure that the monitors are attached appropriately to the patient and do not become dislodged during the night. In addition, an attendant can identify severe OSA so that continuous airway pressure can be instituted in the second part of the night, and the most effective level of CPAP therapy can be determined. These studies are known as “split-night” studies, in which the diagnosis of OSA is established during the first portion of the night and CPAP titration is conducted during the second portion of the night. If successful, this strategy can eliminate the need for an additional polysomnogram for CPAP titration.

Typically, the evaluation of OSA includes sleep staging to assess arousals from sleep and determination of the frequency of apneas and hypopneas from channels measuring oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in the peak signal excursion (airflow) by 90% or more of preevent baseline using an oronasal thermal sensor (diagnostic study), PAP device flow (titration study), or an alternative apnea sensor, for at least 10 seconds. (2) Hypopnea in adults is scored when the peak signal excursions drop by at least 30% of preevent baseline for at least 10 seconds in association with either at least 3% arterial oxygen desaturation or an arousal. The Apnea/Hypopnea Index (AHI) may also be referred to as the Respiratory Disturbance Index (RDI). The AHI is defined as the total number of events per hour of sleep. RDI may be defined as the number of apneas, hypopneas, and RERAs per hour of sleep. When sleep onset and offset are unknown (e.g., in home sleep studies), the RDI may be calculated based on the number of apneas and hypopneas per hour of recording time. A diagnosis of OSA syndrome is accepted when an adult patient has an AHI greater than five and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI equal to or greater than 15 is typically considered moderate OSA, while an AHI greater than 30 is considered severe OSA.

Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as two or more missed breaths, regardless of its duration in seconds. An apnea is scored when peak signal excursions (airflow) drop by at least 90% of preevent baseline using an oronasal thermal sensor (diagnostic study), PAP device flow (titration study), or an alternative sensor; and the event meets duration and respiratory effort criteria for an obstructive, mixed, or central apnea. (2) A hypopnea is scored in children when the peak signal excursions drop is at least 30% of preevent baseline using nasal pressure (diagnostic study) PAP device flow (titration study), or an alternative sensor, for at least the duration of two breaths in association with either a 3% or greater oxygen desaturation or an arousal. In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 or greater is considered severe. Although there is poor correlation between AHI and OSA symptoms, an increase in mortality is associated with an AHI of greater than 15 in adults. Mortality has not been shown to be increased in adult patients with an AHI between five (considered normal) and 15. Sources of measurement error
with PSG include data loss, artifact, event recognition errors, measurement errors, use of different types of leads, and night-to-night variability.

It is estimated that about 7% of adults have moderate or severe OSA, and 20% have at least mild OSA and that the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease. (3) In light of the limited capacity of sleep laboratories, a variety of devices have been developed specifically to evaluate OSA at home. These range from portable full PSG systems to single channel oximeters. Available devices evaluate different parameters, which may include oximetry, respiratory and cardiac monitoring, and sleep/wake activity, but the majority of portable monitors do not record EEG. It has been proposed that unattended studies with portable monitoring devices may improve the diagnosis and treatment of patients with OSA, although the limited number of channels in comparison with full polysomnographic recording may decrease the capability for differential diagnosis or detection of comorbid conditions.

Medical management of OSA includes weight loss, oral appliances, and various types of positive pressure therapy (i.e., fixed CPAP, bilevel positive airway pressure [BiPAP], or auto-adjusting CPAP). CPAP involves the administration of air, usually through the nose, by an external device at a fixed pressure to maintain the patency of the upper airway. BiPAP is similar to CPAP, but these devices are capable of generating two adjustable pressure levels. Auto-adjusting CPAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been hypothesized that both BiPAP and auto-adjusting CPAP are more comfortable for the patient and thus might improve patient compliance or acceptance. In 2010, a nasal expiratory resistance valve (PROVENT®, Ventus Medical) received marketing clearance through the U.S. Food and Drug Administration’s (FDA) 510(k) for the treatment of OSA. PROVENT is a single use device containing valves that are inserted into the nostrils and secured with adhesive. The Winx™ system, which uses oral pressure therapy (OPT) for the treatment of OSA, received marketing clearance in 2012. OPT provides light negative pressure to the oral cavity by using a flexible mouthpiece connected to a bedside console that delivers negative pressure. This device is proposed to increase the size of the retropalatal airway by pulling the soft palate forward and stabilizing the base of the tongue.

Oral appliances can be broadly categorized as mandibular advancing/positioning devices or tongue-retaining devices. Oral appliances can either be “off the shelf” or custom made for the patient by a dental laboratory or similar provider. A number of oral appliances have received marketing clearance through the 510(k) pathway (product code LQZ) for the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™, Lamberg SleepWell-Smarttrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, Desra, Elastomeric Sleep Appliance, Snoemaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device. Surgical management of OSA (i.e., adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in a separate Protocol.

PSG may also be performed in patients with symptoms suggestive of narcolepsy (excessive sleepiness, cataplexy, sleep paralysis, and sleep-related hallucinations), unrefreshing sleep with daytime fatigue/sleepiness but without snoring or witnessed apneas, obesity hypoventilation syndrome (obesity with poor breathing, leading to hypoxia and hypercarbia), parasomnias, periodic limb movements during sleep, sleep-related seizure disorder, and neuromuscular disorders with sleep-related symptoms. The American Academy for Sleep Medicine (AASM) has published guidelines for PSG and related procedures for these indications. (1)

Related Protocol

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome
Policy (Formerly Corporate Medical Guideline)

Diagnosis
A single unattended (unsupervised) home sleep study with a minimum of four recording channels (including oxygen saturation, respiratory movement, airflow, and EKG or heart rate) may be considered medically necessary in adult patients who are at high risk for obstructive sleep apnea (OSA) as described in the Policy Guidelines and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including the following:

- central sleep apnea
- heart failure
- chronic pulmonary disease
- obesity hypoventilation syndrome
- narcolepsy
- periodic limb movements in sleep
- restless leg syndrome.

Unattended (unsupervised) sleep studies are considered investigational in adult patients who are considered at low to moderate risk for OSA.

Unattended (unsupervised) sleep studies are considered investigational in pediatric patients (i.e., less than 18 years of age).

Repeated unattended (unsupervised) home sleep studies with a minimum of four recording channels (including oxygen saturation, respiratory movement, airflow, and EKG/heart rate) may be considered medically necessary in adult patients under the following circumstances:

1. To assess efficacy of surgery or oral appliances/devices; OR
2. To re-evaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued.

Auto-adjusting CPAP may be considered medically necessary during a two-week trial to initiate and titrate CPAP in adult patients with clinically significant OSA.

Supervised polysomnography, performed in a sleep laboratory may be considered medically necessary as a diagnostic test in patients with any of the following (1-3):

1. Observed apneas during sleep; OR
2. A combination of at least two of the following (a-e):
   a. Excessive daytime sleepiness evidenced by an Epworth Sleepiness Scale greater than 10, inappropriate daytime napping (e.g., during driving, conversation, or eating), or sleepiness that interferes with daily activities and is not explained by other conditions (this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children);
   b. Habitual snoring, or gasping/choking episodes associated with awakenings;
   c. Unexplained hypertension;
   d. Obesity, defined as a body mass index greater than 35 kg/m² in adults or greater than the 90th percentile for the weight/height ratio in pediatric patients;
   e. Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease; OR
3. Moderate or severe congestive heart failure, stroke/transient ischemic attack, coronary artery disease, or significant tachycardia or bradyarrhythmic arrhythmias in patients who have nocturnal symptoms suggestive of sleep-related breathing disorder or otherwise are suspected of having sleep apnea.

A repeated supervised polysomnography performed in a sleep laboratory may be considered medically necessary under the following circumstances:

1. To initiate and titrate continuous positive airway pressure (CPAP) in adult patients with clinically significant OSA defined as those patients who have:
   - An apnea/hypopnea index (AHI) of at least 15 per hour, or
   - An AHI of at least five per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

   **Notes:**
   - In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 is considered severe.
   - A split-night study, in which severe OSA is documented during the first half of the study using polysomnography, followed by CPAP during the second half of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines for criteria to perform a split-night study).
   - Respiratory disturbance index may be used in place of apnea/hypopnea index (AHI) in unattended sleep studies.

2. Failure of resolution of symptoms or recurrence of symptoms during treatment; OR
3. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices; OR
4. To re-evaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued.

   **Note:** This statement does not imply that supervised studies are needed routinely following unattended studies. This statement means a re-evaluation based on a substantial change in symptoms or in the clinical situation.

Multiple consecutive nights of supervised or unattended (unsupervised) sleep studies that do not meet the above criteria for repeat studies are **not medically necessary**.

The use of an abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies is considered investigational.

Multiple sleep latency testing is considered not medically necessary in the diagnosis of OSA except to exclude or confirm narcolepsy in the diagnostic workup of OSA syndrome.

Remote monitoring is considered not medically necessary.

**Medical Management**

CPAP may be considered medically necessary in adult or pediatric patients with clinically significant OSA.

As noted above, auto-adjusting CPAP may be considered medically necessary during a two-week trial to initiate and titrate CPAP in adult patients with clinically significant OSA.

Bilevel positive airway pressure or auto-adjusting CPAP may be considered medically necessary in patients with clinically significant OSA and who have failed a prior trial of CPAP or for whom BiPAP is found to be more effective in the sleep lab.

Intraoral appliances (tongue retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in patients with clinically significant OSA under the following conditions:
• OSA, defined by an apnea/hypopnea index (AHI) of at least 15 per hour, or an AHI of at least five events per hour in a patient with excessive daytime sleepiness or unexplained hypertension, AND
• A trial with CPAP has failed or is contraindicated, AND
• The device is prescribed by a treating physician, AND
• The device is custom-fitted by qualified dental personnel, AND
• There is absence of temporomandibular dysfunction or periodontal disease.

Note: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for patients with severe OSA, as oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-moderate OSA. Therefore, it is particularly important that patients with severe OSA should have an initial trial of CPAP and that all reasonable attempts are made to continue treatment with CPAP, prior to the decision to switch to an oral appliance.

Nasal expiratory positive airway pressure (EPAP) and oral pressure therapy devices are considered investigational.

Policy Guidelines

The multiple sleep latency test (MSLT) is an objective measure of the tendency to fall asleep in the absence of alerting factors, while the maintenance of wakefulness test (MWT) is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). (4) The MSLT and MWT are not routinely indicated in the evaluation and diagnosis of OSA, or in assessment of change following treatment with CPAP. The MSLT may be indicated as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis (often characterized by cataplexy, sleep paralysis, and hypnagogic/hypnopompic hallucinations) or to differentiate between suspected idiopathic hypersomnia and narcolepsy. Narcolepsy and OSA can co-occur. (4, 5) Since it is not possible to differentiate the excessive sleepiness caused by OSA and narcolepsy, the OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.

The presentation of obstructive sleep apnea (OSA) in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness, and an apnea/hypopnea index (AHI) greater than 1.5 is considered abnormal (an AHI of 15 is considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. Continuous positive airway pressure (CPAP) is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

The medical professional who is interpreting a polysomnogram or home sleep study should have training in sleep medicine and review the raw data from PSG and home sleep studies in order to detect artifacts and data loss. In addition, the treatment of patients diagnosed with OSA should be initiated and monitored by a professional with training in sleep medicine. It is important to monitor symptoms and adherence to positive airway pressure (PAP) treatment, e.g., review of symptoms and device utilization between 30 and 90 days.

Although not an exclusive list, patients with all four of the following symptoms are considered to be at high risk for OSA:

• habitual snoring;
• observed apneas;
• excessive daytime sleepiness;
• a body mass index greater than 35.

If no bed partner is available to report snoring or observed apneas, other signs and symptoms suggestive of OSA, (e.g., age of the patient, male gender, thick neck, or craniofacial or upper airway soft tissue abnormalities) may
be considered. Objective clinical prediction rules are being developed, however, at the present time risk assessment is based on clinical judgment. (1, 3) Overnight oximetry has been used by some sleep specialists as a component of the risk assessment, but is not adequate for the diagnosis of OSA. Therefore, a follow-up PSG or home sleep study would still be required to confirm or exclude a diagnosis of OSA.

American Academy for Sleep Medicine (AASM) Practice Parameters indicate that a split-night study (initial diagnostic polysomnography [PSG] followed by CPAP titration during PSG on the same night) is an alternative to one full night of diagnostic PSG followed by a second night of titration if the following four criteria are met (1):

a. An AHI of at least 40 is documented during a minimum of two hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI of 20 to 40, based on clinical judgment (e.g., if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP pressure requirements, based on split-night studies, may be less accurate than in full-night calibrations.

b. CPAP titration is carried out for more than three hours (because respiratory events can worsen as the night progresses).

c. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM (NREM) sleep, including REM sleep with the patient in the supine position.

d. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder (SRBD) is confirmed but criteria b and c are not met.

In the 2005 practice parameters of the American Academy of Sleep Medicine (1), there are four types of monitoring procedures: type 1, standard attended in-lab comprehensive polysomnography; type 2, comprehensive portable polysomnography; type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of four or more channels of monitoring; and type 4, continuous single or dual bioparameters, consisting of one or two channels, typically oxygen saturation, or airflow. Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and polysomnography are often used interchangeably. Polysomnography is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the patient’s home.

Cardiorespiratory sleep studies without EEG may be called polygraphic studies, and can either be attended or unattended by a technologist. A wide variety of portable monitors and proprietary automated scoring systems are being tested and marketed, but the optimum combination of sensors and scoring algorithms is currently unknown. Current recommendations are that the portable monitoring device have four channels (oxygen saturation, respiratory effort, respiratory airflow, and heart rate), and allow review of the raw data. Type IV monitors with fewer than three channels are not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional with training in sleep medicine in order to detect artifacts and data loss.

Medicare Advantage

For Medicare Advantage, diagnostic testing is medically necessary for patients with symptoms or complaints of:

- Narcolepsy, which is usually confirmed by an overnight sleep study (polysomnography) followed by a multiple sleep latency test (MSLT)
- Sleep Apnea, which is confirmed by Type I, II, III, IV as described in the following section:
Follow-up polysomnography or home sleep studies is not routinely necessary for patients treated with CPAP whose symptoms continue to resolve. However follow up testing may be medically necessary in the following circumstances:

- After substantial weight loss to ascertain whether CPAP is still needed
- After substantial weight gain in patients previously successfully treated with CPAP who are again symptomatic despite continued use of CPAP, to determine if adjustments are needed
- When clinical response is insufficient or symptoms return

- Parasomnia, when seizure disorder as a cause has been ruled out and the episodes result in harm to the patient or others.

A CPAP device is considered **medically necessary** when used in adults with OSA that meet the criteria below*, when diagnosed by an appropriate sleep test (Type I, II, III, or IV). An appropriate sleep test would be either a polysomnogram performed in a facility-based laboratory (Type I study) or a home sleep test (HST) (Types II, III, or IV). The test must be ordered by the patient’s treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

A Type I sleep test is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It is facility-based and must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), and electro-oculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

An HST is performed unattended in the beneficiary’s home using a portable monitoring device. A portable monitoring device for conducting an HST must meet one of the following criteria:

A. Type II device – Monitors and records a minimum of seven (7) channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory movement/effort and oxygen saturation; or,

B. Type III device – Monitors and records a minimum of four (4) channels: two respiratory movement/effort, airflow, ECG/heart rate and oxygen saturation; or,

C. Type IV device – Monitors and records a minimum of three (3) channels that allows calculation of an AHI or RDI as defined above. Devices that record channels that do not allow direct calculation of an AHI or RDI may be considered as acceptable alternatives if there is substantive clinical evidence in the published peer-reviewed medical literature that demonstrates that the results accurately and reliably correspond to an AHI or RDI. This determination will be made on a device by device basis. Currently there is no device that indirectly measures AHI or RDI that meets this criterion.

All patients who undergo a HST must, prior to having the test, receive a demonstration of how to properly apply a portable sleep monitoring device. This education must be provided by the entity conducting the HST and may not be performed by a DME supplier. Patient instruction can be by either face-to-face demonstration or by video or telephonic instruction, with 24 hour availability of qualified personnel to answer questions or troubleshoot issues with the device.

For all non-hospital based facilities, the facility must have on file documentation that it is in compliance with the criteria set by the American Sleep Disorders Association, the American Academy of Sleep Medicine or the Accreditation Commission for Health Care, Inc. Failure to supply such documentation may result in denial of the claim. Medicare does not cover sleep studies performed in mobile sleep laboratories.
The sleep laboratory or testing facility must be affiliated with a hospital or be under the direction and control of a physician (MD/DO), even though the diagnostic test may be performed in the absence of direct physician supervision. The laboratory-physician director must be:

- Board-certified in sleep medicine (ABSM, i.e., Diplomate of, or board-eligible for, the American Board of Sleep Medicine); or
- Diplomate or board-eligible for an American Board of Medical Specialties (ABMS) approved board; or
- Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself, and only until the time of reporting of the first examination for which the physician is eligible; or
- An active staff member of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) the Accreditation Commission for Health Care, Inc. or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]).

HST scoring must be performed by an individual certified by the Board of Registered Polysomnographic Technologists as a Registered Polysomnographic Technologist (RPSGT), or equivalent, or by a polysomnographic technician under the supervision of a RPSGT, or equivalent. RPSGTs and polysomnographic technicians must meet the standards for such individuals promulgated by the American Academy of Sleep Medicine Standards for Accreditation of Laboratories for Sleep Related Breathing Disorders, or by the Accreditation Commission for Health Care, Inc. Standards for Accreditation for Sleep Programs and be licensed or certified by the state in which they practice, if such licensure or certification exists. The laboratory physician must review the entire raw data recording for every patient studied.

No aspect of an HST, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.

HST is not medically appropriate for patients with the following comorbidities:
- Moderate to severe pulmonary disease (e.g., patients on oxygen or regular bronchodilator use)
- Neuromuscular disease affecting muscles of respiration
- Congestive heart failure
- Suspicion of the presence of other sleep disorders.

*CPAP (PAP) Criteria

Medical records of the treating physician and the supplier must support medical appropriateness:
A single level continuous positive pressure device is medically necessary for the treatment of obstructive sleep apnea (OSA) if criteria A-C are met:
A. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea.
B. The patient has a Medicare-covered sleep test that meets either of the following criteria (1 or 2):
   1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
   2. The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
      a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
      b. Hypertension, ischemic heart disease, or history of stroke.
C. The patient and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.

A bi-level respiratory assist device (RAD) is medically necessary for those patients with OSA who meet criteria A-C in addition to the single level positive pressure device having been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

A bi-level positive airway pressure device with back-up rate is not medically necessary, if the primary diagnosis is OSA.

Medical appropriateness of a PAP device beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating physician must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy. Clinical benefit is demonstrated by:
1. Face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and,
2. A data report from the PAP device which documents evidence of adherence to use of the PAP device, reviewed by the treating physician.

Adherence to therapy is defined as use of PAP ≥ four hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.

Patients who fail the initial 12 week trial are eligible to re-qualify for a PAP device but must have both:
- Face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; and
- Repeat sleep test in a facility-based setting (Type 1 study).

If the physician re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the patient is benefiting from PAP therapy as defined in criteria 1 and 2 above, continued coverage of the PAP device will commence with the date of that re-evaluation.

If a CPAP device is tried and found ineffective during the initial three month home trial, substitution of a RAD does not change the length of the trial unless there is less than 30 days remaining in the trial period. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31st and 91st day following the initiation of CPAP.

If a CPAP device was used for more than three months and the patient was switched to a RAD, then the clinical re-evaluation would occur between the 31st and 91st day following the initiation of the RAD. There would also need to be documentation of adherence to therapy during the three month trial with the RAD.

If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies. Replacement after five years requires that the treating physician document that the patient uses and has benefit from the PAP device.

Claims would be billed to original Medicare for Medicare Advantage members not meeting the medical necessity criteria for PAP therapy (indicated above), but meeting Medicare’s criteria for coverage under a clinical trial.

Oral Appliances

A custom fabricated mandibular advancement oral appliance used to treat OSA is medically necessary if criteria A-D are met:
A. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea testing.

B. The patient has a Medicare-covered sleep test that meets either of the following criteria (1-3):
   1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
   2. The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
      a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
      b. Hypertension, ischemic heart disease, or history of stroke; or,
   3. If the AHI > 30 or the RDI > 30 and meets either of the following (a or b):
      a. the patient is not able to tolerate a positive airway pressure (PAP) device or
      b. the treating physician determines that the use of a PAP device is contraindicated.

C. The device is ordered by the treating physician following review of the report of the sleep test. (The physician who provides the order for the oral appliance could be different from the one who performed the clinical evaluation in criterion A.)

D. The device is provided and billed for by a licensed dentist (DDS or DMD).

Replacement of medically necessary oral appliances:

Oral appliances are eligible for replacement at the end of their five-year reasonable useful lifetime (RUL). These items may be replaced prior to the end of the five-year RUL in cases of loss, theft, or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). Replacement due to wear-and-tear as the result of everyday use will be denied as non covered prior to the expiration of the five-year RUL.

Custom fabricated appliances that achieve their effect through positioning of the tongue are considered dental and therefore not covered.

A prefabricated oral appliance is considered investigational.

References

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


59. CMS NCD for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1), Implementation Date 8/10/2009.

60. National Government Services (NGS) Local Coverage Determination (LCD) for Polysomnography and Sleep Studies (L26428), Revision Effective Date For services performed on or after 10/01/2012.

61. NHIC Local Coverage Determination (LCD) for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L11528), Revision Effective Date For services performed on or after 10/01/2013.

62. NHIC LCD for Oral Appliances for Obstructive Sleep Apnea (L28603), Revision Effective Date For services performed on or after 07/01/2012.

63. NHIC Local Coverage Article for LCD: Oral Appliances for Obstructive Sleep Apnea, effective July 2012 (A50417).