



Criteria for Benefit Decisions Related to Polysomnography:

Criteria for Approval:

Sleep studies and polysomnography refer to the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for 6 or more hours with physician review, interpretation and report. The studies are performed to diagnose a variety of sleep disorders and to evaluate a patient's response to therapies such as continuous positive airway pressure (CPAP).

Polysomnography is distinguished from sleep studies by the inclusion of sleep staging.

Polysomnography is defined to include, but is not limited to the following:

- A 1-4 lead electroencephalogram (EEG) to measure global neural encephalographic activity using electrodes placed on the scalp
- Electrooculogram (EOG) to measure eye movements using electrodes placed near the outer canthus of each eye
- A submental electromyogram (EMG) to measure submental electromyographic activity using electrodes placed over the mentalis, submental muscle and/or masseter regions
- Rhythm electrocardiogram (ECG) with two or three chest leads
- Nasal and/or oral airflow via mercury switches or by direct observation
- Ventilation and respiratory effort by chest-wall and abdominal movement measured using strain gauges, piezoelectric belts, inductive plethysmography, impedance or inductance pneumography, endoesophageal pressure, or by intercostal EMG
- Gas exchange (oxygen saturation (SpO₂)) by oximetry, transcutaneous monitoring, or end-tidal gas analysis
- Extremity muscle activity, motor activity-movement using EMG
- Body positions via mercury switches or by direct observation
- Recordings of vibration (frequency and/or volume) may be recorded
- Transcutaneous CO₂, esophageal pH, penile tumescence and bipolar EEG

Multiple Sleep Latency Testing (MSLT)

Multiple sleep latency testing (MSLT) involves several 20-minute nap opportunities offered at 2-hour intervals. MSLT objectively assesses sleep tendency by measuring the number of minutes it takes the patient to fall asleep. Conversely, the maintenance of wakefulness test (MWT) requires the patient to try to stay awake. MSLT is the better test for demonstration of sleep-onset REM periods, a determination that is important in establishing the diagnosis of narcolepsy. To insure validity, proper interpretation of the MSLT

Criteria for Benefit Decisions Related to Polysomnography - Continued

can only be made following a polysomnography performed on the preceding night.

Criteria for Coverage of Diagnostic Tests

All reasonable and necessary diagnostic tests given for the medical conditions are covered when the following criteria are met:

- The clinic is either affiliated with a hospital or is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder clinics may be covered even in the absence of direct supervision by a physician;
- Patients are referred to the sleep disorder clinic by their attending physicians, and the clinic maintains a record of the attending physician's orders; and
- The need for diagnostic testing is confirmed by medical evidence, e.g., physician examinations and laboratory tests.

Medical Conditions for Which Testing is Covered

1. Narcolepsy - This term refers to a syndrome that is characterized by abnormal sleep tendencies, e.g., excessive daytime sleepiness or disturbed nocturnal sleep. Related diagnostic testing is covered if the patient has inappropriate sleep episodes or attacks (e.g., while driving, in the middle of a meal, in the middle of a conversation), amnesiac episodes, or continuous disabling drowsiness. The sleep disorder clinic must submit documentation that this condition is severe enough to interfere with the patient's well being and health before Medicare benefits may be provided for diagnostic testing. Ordinarily, a diagnosis of narcolepsy can be confirmed by three sleep naps. If more than three sleep naps are claimed, ... persuasive medical evidence justifying the medical necessity for the additional test(s) [will be required].

The diagnosis of narcolepsy is usually confirmed by an overnight sleep study (polysomnography) followed by a multiple sleep latency test (MSLT). The following measurements are normally required to diagnose narcolepsy:

- Polysomnographic assessment of the quality and quantity of nighttime sleep;
- Determination of the latency of the first REM episode;
- MSLT; and
- The presence of REM-sleep episodes.

Initial polysomnography and MSLT occasionally fail to identify narcolepsy. Repeat polysomnography may be indicated:

- If the first study is technically inadequate due to equipment failure;
- If the subject could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;
- If initiation of therapy or confirmation of the efficacy of prescribed therapy is needed; or
- If the results were inconclusive or ambiguous.

2. Sleep Apnea - This is a potentially lethal condition where the patient stops breathing during sleep. Three types of sleep apnea have been described (central, obstructive, and mixed). The nature of the apnea episodes can be documented by appropriate diagnostic testing. Ordinarily, a single polysomnogram and electroencephalogram (EEG) can diagnose sleep apnea. If more than one such testing session is claimed,

Criteria for Benefit Decisions Related to Polysomnography - Continued

persuasive medical evidence justifying the medical necessity for the additional tests will be required.

The diagnosis of sleep apnea may be made using the following Polysomnography performed in a sleep laboratory. Sleep apnea may be due to an occlusion of the airway (obstructive apnea), absence of respiratory effort (central sleep apnea) or a combination of these factors (mixed sleep apnea).

Obstructive sleep apnea (OSA) may be caused by one of the following:

- Reduced upper airway caliber due to obesity
- Adenotonsillar hypertrophy
- Mandibular deficiency
- Macroglossia
- Upper airway tumor
- Excessive pressure across the collapsible segment of the upper airway
- Activity of the muscles of the upper airway insufficient to maintain patency.

A positive test for OSA is established if either of the following criterion using the Apnea-Hypopnea Index (AHI) or Respiratory Distress Index (RDI) are met:

- **AHI or RDI greater than or equal to 15 events per hour, or**
- **AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.**

The AHI is equal to the average number of episodes of apnea and hypopnea per hour.

The RDI is equal to the average number of respiratory disturbances per hour.

If the AHI or RDI is calculated based on less than two hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing is at least the number of events that would have been required in a two hour period.

3. Parasomnia - Parasomnias are a group of conditions that represent undesirable or unpleasant occurrences during sleep. Behavior during these times can often lead to damage to the surroundings and injury to the patient or to others. Parasomnia may include conditions such as sleepwalking, sleep terrors, and rapid eye movement (REM) sleep behavior disorders. In many of these cases, the nature of these conditions may be established by careful clinical evaluation. Suspected seizure disorders as possible cause of the parasomnia are appropriately evaluated by standard or prolonged sleep EEG studies. In cases where seizure disorders have been ruled out and in cases that present a history of repeated violent or injurious episodes during sleep, polysomnography may be useful in providing a diagnostic classification or prognosis. (CMS Publication 100-2, Medicare Benefit Policy Manual, Chapter 15, Section 70).

Normally, a clinical history, neurologic examination, and routine EEG obtained while the patient is awake and asleep are often sufficient to establish the diagnosis and permit the appropriate treatment of sleep-related epilepsy. In addition, common, uncomplicated, non-injurious parasomnias, such as typical disorders of arousal, nightmares, enuresis, somniloquy, and bruxism can usually be diagnosed by clinical evaluation alone.

Polysomnography is indicated to provide a diagnostic classification or prognosis when both of the following exist:

Criteria for Benefit Decisions Related to Polysomnography - Continued

- When the clinical evaluation and results of standard EEG have ruled out a seizure disorder, and
- In cases that present a history of episodes during sleep that result in harm to the patient or others.

When polysomnography is performed for the diagnosis of parasomnias, the following measurements are obtained:

- Sleep-scoring channels (EEG, EOG, Chin EMG);
- EEG using an expanded bilateral montage;
- EMG for body movements;
- Audiovisual recording; and
- Documented technologist observations.

Limitations

Diagnostic testing that is duplicative of previous sleep testing performed to the extent that the previous results are still pertinent is not covered, because it is not reasonable and necessary if there have been no significant clinical changes in the patient's medical history since the previous study.

Polysomnography, cardiorespiratory sleep studies, and MSLT are not covered in the following situations:

- For the diagnosis of patients with chronic insomnia
- To preoperatively evaluate a patient for laser-assisted uvulopalatopharyngoplasty without clinical evidence that obstructive sleep apnea is suspected;
- To diagnose chronic lung disease (nocturnal hypoxemia in patients with chronic, obstructive, restrictive or reactive lung disease is usually adequately evaluated by oximetry; however, if the patient's sign/symptoms suggest a diagnosis of obstructive sleep apnea, polysomnography may be considered medically necessary);
- In cases where seizure disorders have not been ruled out,
- In cases of typical, uncomplicated and non-injurious parasomnias when the diagnosis is clearly delineated;
- For patients with epilepsy who have no specific complaints consistent with a sleep disorder;
- For patients with symptoms suggestive of periodic limb movement disorder or restless leg syndrome unless symptoms are suspected of being related to a covered indication;
- For the diagnosis of insomnia related to depression;
- For the diagnosis of circadian rhythm sleep disorders (i.e., rapid time-zone change [jet lag], shift-work sleep disorder, delayed sleep phase syndrome, advanced sleep phase syndrome, and non-24 hour sleep/wake disorder).

Documentation Requirements

The medical record must document signs and symptoms to support reasonable and necessary indications for performing a sleep study and must be available upon request.

These signs or symptoms should include, but are not limited to: daytime somnolence, witnessed apneic episodes, reports of sleeping/napping during the day, falling asleep at work or when driving.

Criteria for Benefit Decisions Related to Polysomnography - Continued

The patient's medical record must contain documentation that fully supports the medical necessity and frequency for overnight sleep studies. This documentation includes, but is not limited to, relevant medical history, physical examination and results of pertinent diagnostic tests or procedures.

For services to be reported as sleep studies or polysomnography, the patient must sleep six or more hours, with physician review, interpretation and report of the study.

The following minimal information must be included in the sleep disorders evaluation report:

- Parameters monitored;
- Start time and duration of day/night of study;
- Total sleep time, sleep efficiency, number/duration of awakenings;
- For tests involving sleep staging: time and percent time spent in each stage;
- For tests monitoring sleep latency or maintenance of wakefulness testing: latency to both NREM and REM sleep;
- Individual sub-test sleep latencies, mean sleep latency, and the number of REM occurrences on MSLT;
- Respiratory patterns including type (central/obstructive/periodic), number and duration, effect on oxygenation, sleep stage/body position relationship, and response to any diagnostic/therapeutic maneuvers;
- Cardiac rate/rhythm and any effect of sleep disordered breathing on EKG;
- Detailed behavioral observations; and
- EEG or EMG abnormalities.

The sleep clinic 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. This information must be documented and available upon request. It is recommended that the clinic physician director have a sufficient understanding of sleep disorders as evidenced by completion of a pulmonary fellowship or a sleep fellowship, and is either a diplomat or board-eligible for the American Board of Sleep Medicine.

The patient is to be referred to the clinic by the attending physician. The physician's order must be kept in the medical record.

The sleep disorder clinic must maintain and provide, when requested, sufficient documentation that narcolepsy is severe enough to interfere with the patient's well being and health before benefits are provided for diagnostic testing.

If more than two nights of testing are performed, documentation justifying the medical necessity for the additional test(s) must be available in the patient's medical record.

REFERENCE:

LDC LCD for Polysomnography and Sleep Studies (L26428): Centers for Medicare & Medicare Services http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=26428&lcd_version=19&show=all

Last accessed 06/09/2009.

HAYES Medical Technology Directory™. Sleep Apnea Treatment, Devices. Lansdale PA: HAYES, Inc. © 2008 Winifred S. Hayes, INC. 1999 September. Last accessed 6/9/2009.

Criteria for Benefit Decisions Related to Polysomnography - Continued

U.S. Preventive Services Task Force, <http://www.ahrq.gov/clinic/sleep2.htm>, last accessed 06/09/2009.