Summary

Polysomnography (PSG) is a recording of multiple physiologic parameters relevant to sleep. Videorecording (Video PSG) may also be performed during PSG to assess parasomnias such as REM sleep behavior disorder (RBD). This document addresses PSG for non-respiratory sleep disorders, which include the hypersomnias (eg, narcolepsy), parasomnias, and movement disorders (eg, restless legs syndrome [RLS] and periodic limb movement disorder [PLMD]).

The evidence for polysomnography (PSG) in patients suspected of having a benign parasomnia or restless legs syndrome (RLS) consists of systematic reviews of studies on diagnostic accuracy, case series, and controlled cohort studies. Outcomes of interest are test accuracy, symptoms, functional outcomes, and quality of life. The evidence indicates that typical parasomnias such as sleepwalking or sleep terrors may be diagnosed on the basis of their clinical features and do not require PSG. The movement disorder RLS also does not require PSG, since the principle symptoms of RLS occur during wake as well as during sleep and therefore PSG results are generally not useful. The evidence is sufficient to determine qualitatively that the technology is unlikely to improve the net health outcome.

The evidence for PSG in patients suspected of having narcolepsy, a violent or potentially injurious parasomnia, or periodic limb movement disorder (PLMD) consists of systematic reviews of studies on diagnostic accuracy, case series, and controlled cohort studies. Outcomes of interest are test accuracy, symptoms, functional outcomes, and quality of life. Evidence indicates that PSG followed by the multiple sleep latency test (MSLT) is associated with moderate sensitivity and high specificity for the diagnosis of narcolepsy. For the diagnosis of RBD, combined use of clinical history and PSG to document loss of muscle atonia during REM sleep increases diagnostic accuracy and is considered the gold standard for diagnosis. PSG with electromyography (EMG) of the anterior tibialis is the only method available to diagnose PLMD, but this sleep-related movement disorder is rare and should only be evaluated by PSG if there are no other sleep disorders present. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Related Policies

2.01.18 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome
Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Polysomnography (PSG) and a multiple sleep latency test (MSLT) performed on the day after the PSG may be considered **medically necessary** in the evaluation of suspected narcolepsy or idiopathic hypersomnia.

PSG may be **medically necessary** when evaluating patients with parasomnias when there is a history of sleep related injurious or potentially injurious disruptive behaviors.

PSG may be **medically necessary** when a diagnosis of periodic leg movements of sleep disorder (PLMD) is considered when there is:

- A complaint of repetitive limb movement during sleep by the patient or an observer; AND
- No other concurrent sleep disorder; AND
- At least one of the following is present:
  - Frequent awakenings; OR
  - Fragmented sleep; OR
  - Difficulty maintaining sleep; OR
  - Excessive daytime sleepiness

PSG for the diagnosis of PLMD is considered **not medically necessary** when there is concurrent untreated obstructive sleep apnea, restless legs syndrome, narcolepsy, or REM sleep behavior disorder.

PSG is considered **investigational** for the diagnosis of non-respiratory sleep disorders not meeting the criteria above.

Background

Polysomnography (PSG) is a recording of multiple physiologic parameters relevant to sleep. The standard full polysomnogram includes:

- Electroencephalography (EEG) to differentiate the various stages of sleep and wake,
- Chin electromyography (EMG) and electrooculography (EOG) to assess muscle tone and detect rapid eye movement (REM) sleep,
- Respiratory effort, airflow, blood oxygen saturation (oximetry) and electrocardiography (ECG) to assess apneic events,
- Anterior tibialis EMG to assess periodic limb movements (PLMs) during sleep, and
- Video recording to detect any unusual behavior.

Videorecording (Video-PSG) may also be performed during PSG to assess parasomnias (eg sleep walking and REM behavior disorder). This document addresses PSG for non-respiratory sleep disorders.
disorders, which include the hypersomnias (eg narcolepsy), parasomnias, and movement disorders (eg restless legs and periodic limb movement disorder).

Hypersomnias

The hypersomnias include such disorders as narcolepsy, Klein-Levine syndrome, and idiopathic hypersomnolence. Narcolepsy is a neurologic disorder characterized predominantly by abnormalities of REM sleep, some abnormalities of NREM sleep, and the presence of excessive daytime sleepiness that cannot be fully relieved by any amount of sleep. The classic symptoms include hypersomnolence, cataplexy, sleep paralysis, and hypnagogic (onset of sleep) hallucinations. Cataplexy refers to the total or partial loss of muscle tone in response to sudden emotion. The majority of patients with cataplexy have abnormally low levels of hypocretin-1 (orexin A) in the cerebrospinal fluid (CSF).\(^1\) Narcolepsy type 1 (narcolepsy with cataplexy) is defined as excessive daytime sleepiness (EDS) and at least one of the following criteria: a) hypocretin deficiency or b) cataplexy and a positive multiple sleep latency test (MSLT). In the MSLT the patient lies down in a dark quiet room to assess the time to enter the different stages of sleep. The test is repeated every 2 hours throughout the day and the maximum time allowed to fall sleep is typically set at 20 minutes. Patients with narcolepsy often have a mean sleep latency of less than 5 minutes and 2 or more early onset REM periods during the MSLT naps. People with idiopathic hypersomnia fall asleep easily but typically do not reach REM sleep during the MSLT. Narcolepsy type 2 (narcolepsy without cataplexy) is defined by chronic sleepiness plus a positive MSLT; hypocretin-1 levels are in the normal range in a majority of patients.

Parasomnias

Parasomnias are abnormal behavioral, experiential, or physiological events that occur during entry into sleep, within sleep, or during arousals from sleep. Parasomnias can result in a serious disruption of sleep-wake schedules and family functioning. Some, particularly sleepwalking, sleep terrors, and REM sleep behavior disorder, can cause injury to the patient and others. Parasomnias are classified into parasomnias associated with REM sleep, parasomnias associated with non-REM sleep, and other parasomnias.

Parasomnias Associated with REM sleep

REM sleep is normally accompanied by muscle atonia, in which there is an almost complete paralysis of the body through inhibition of motor neurons. In patients with REM Sleep Behavior Disorder (RBD) muscle tone is maintained during REM sleep. This can lead to abnormal or disruptive behaviors associated with vivid dreams such as talking, laughing, shouting, gesturing, grabbing, flailing arms, punching, kicking, sitting up or leaping from bed, and running.\(^2\) Violent episodes that carry a risk of harm to the patient or bed partner may occur up to several times nightly. Idiopathic RBD is associated with the development of degenerative synucleinopathies (Parkinson disease, dementia with Lewy bodies, and multiple systems atrophy) in about half of patients. Guidelines recommend maintaining a safe sleeping environment for both the patient and bed partner along with medical therapy. Other parasomnias associated with REM sleep are Recurrent Isolated Sleep Paralysis and Nightmare Disorder.
**Parasomnias Associated with non-REM sleep**

Disorders of arousal from NREM sleep result from the intrusion of wake into NREM sleep. These include Confusional Arousals, Sleepwalking, and Sleep Terrors. In these parasomnias, the patient has incomplete awakening from NREM sleep, usually appears awake with eyes open, is unresponsive to external stimuli, and is amnestic to the event. Sleepwalking can range from calm behaviors such as walking through a house to violent and/or injurious behaviors such as jumping out of a second story window. Patients with Sleep Terrors (also called Night Terrors) typically awaken with a loud scream and feeling of intense fear, jump out of bed, and occasionally may commit a violent act.

**Other Parasomnias**

The category of “other parasomnias” has no specific relationship to sleep stage and includes Sleep-related Dissociative Disorders, Sleep-related Enuresis, Sleep-related Groaning, Exploding Head Syndrome, Sleep-related Hallucinations, and Sleep-related Eating Disorder. Diagnosis of these disorders is primarily clinical, although PSG may be used for differential diagnosis.

- In Sleep-related Dissociative Disorders, behaviors occur during an awakening but the patient is amnestic to them.
- Sleep-related Enuresis (bedwetting) is characterized by recurrent involuntary voiding in patients greater than 5 years of age.
- Sleep-related Groaning is a prolonged vocalization that can occur during either NREM or REM sleep.
- Exploding Head Syndrome is a sensation of a sudden loud noise or explosive feeling within the head upon falling asleep or during an awakening from sleep.
- Sleep-related Hallucinations are hallucinations that occur upon falling asleep or upon awakening.
- Sleep-related Eating Disorder is characterized by recurrent episodes of arousals from sleep with involuntary eating or drinking. Patients may have several episodes during the night, typically eat foods that they would not eat during the day, and may injure themselves by cooking during sleep.

**Sleep-Related Movement Disorders**

Sleep-related movement disorders include restless legs syndrome (RLS) and periodic limb movement disorder (PLMD).

**RLS**

RLS is a neurologic disorder characterized by uncomfortable or odd sensations in the leg that usually occur during periods of relaxation, such as while watching television, reading, or attempting to fall asleep. Symptoms occur primarily in the evening. The sensations are typically described as creeping, crawling, itchy, burning, or tingling. There is an urge to move in an effort to relieve these feelings, which may be partially relieved by activities such as rubbing or slapping the leg, bouncing the feet, or walking around the room.
**PLMD**

Periodic limb movements (PLMs) are involuntary, stereotypic, repetitive limb movements during sleep, which most often occur in the lower extremities, including the toes, ankles, knees, and hips, and occasionally in the upper extremities. The repetitive movements can cause fragmented sleep architecture, with frequent awakenings, a reduction in slow wave sleep and decreased sleep efficiency, leading to excessive daytime sleepiness. PLMD alone is thought to be rare as PLMS are typically associated with RLS, RBD, or narcolepsy and represent a distinct diagnosis from PLMD.  

**Regulatory Status**

A large number of polysomnography devices have been cleared since 1986. FDA product code: OLV.

**Rationale**

This policy was created in 2015, based in part on evidence reviewed by the American Academy of Sleep Medicine (AASM, previously the American Sleep Disorders Association) and a search of the MEDLINE database through July 7, 2015.

**Hypersomnias**

Evidence reviewed by the AASM included a data review of 1,602 patients, of which 176 patients had narcolepsy and 1,426 had other sleep disorders. In patients with clinical narcolepsy, 2 or more sleep onset REM periods (SOREMS) had a sensitivity of 41% and predictive value of 57%. The presence of 3 or more SOREMS had a sensitivity of 41% and specificity of 98.8%. However, 7% of obstructive sleep apnea (OSA) patients and 5% of other sleep disorders patients had 2 SOREMs on MSLT, leading to a low predictive value for narcolepsy. No body of data was found that validated the maintenance of wakefulness test (MWT – which measures the patient’s ability to stay awake in a quiet sleep-inducing environment), limited or partial PSG, portable recording, isolated MSLT, or separately performed PSG and MSLT as an alternative to the “gold standard” of nocturnal PSG with an MSLT on the following day for the diagnosis of narcolepsy. The 2005 evidence review found that the presence of 2 or more early sleep-onset latency episodes was associated with a sensitivity of 0.78 and specificity of 0.93 for the diagnosis of narcolepsy. Based on the evidence reviewed, the updated 2005 AASM guidelines indicated that polysomnography (PSG) is used to rule out other potential causes of sleepiness followed by a multiple sleep latency test (MSLT) to confirm the clinical impression of narcolepsy. These tests assume greater significance if cataplexy is lacking. In the absence of cataplexy and when there is one or more of the other symptoms, the laboratory criteria are required to establish the diagnosis of narcolepsy.

**Parasomnias**

Evidence reviewed by the AASM in 1997 indicated that typical sleepwalking or sleep terrors, with onset in childhood, a positive family history, occurrence during the first third of the night, amnesia for the events, prompt return to sleep following the events, and relatively benign automatistic behaviors, may
be diagnosed on the basis of their historic clinical features. This conclusion was based upon very consistent descriptive literature (case series and cohort studies). However, when the events are not typical of benign partial arousals and where other diagnoses, prognoses, and interventions should be considered, PSG was recommended. The evidence reviewed in 1997 included only 3 articles on disorders of arousal and 2 for RBD that included comparison data for normal controls. Most of the articles supporting the utility of PSG were limited by biases inherent in uncontrolled clinical reports. The need for PSG was also indicated in a 2011 review of parasomnias that concluded that although RBD is the only parasomnia that requires PSG for diagnosis, PSG may be needed to rule out another sleep pathology, such as sleep disordered breathing or periodic limb movements (PLMs) of sleep, that might cause a parasomnia.

Evidence reviewed in a 2010 AASM Best Practice Guide indicates that sleep related injuries are a significant portion of the morbidity in REM sleep behavior disorder (RBD), with a prevalence in diagnosed RBD patients ranging from 30% to 81%. Types of injuries ranged from ecchymoses and lacerations to fractures and subdural hematomas, with ecchymoses and lacerations being significantly more common than fractures. In a series of 92 patients, 64% of the bed partners sustained punches, kicks, attempted strangulation, and assault with objects. Minimal diagnostic criteria for RBD requires the presence of REM sleep without atonia, defined as sustained or intermittent elevation of submental electromyogram (EMG) tone or excessive phasic muscle activity in the limb EMG. Two clinical series with over 100 cases each of patients with various parasomnias found that PSG had an overall yield of clinical utility in 65% and 91% of cases. A systematic review on the diagnosis of RBD found that diagnostic accuracy is increased with the combined use of clinical history and video PSG to document the intermittent or sustained loss of muscle atonia or actual observation of RBD occurrences.

Sleep-Related Movement Disorders

The four cardinal diagnostic features of restless legs syndrome (RLS) include (1) an urge to move the limbs that is usually associated with paresthesias or dysesthesias, (2) symptoms that start or become worse with rest, (3) at least partial relief of symptoms with physical activity, and (4) worsening of symptoms in the evening or at night. Evidence reviewed by the AASM included a case–control study which found that compared to controls, RLS patients had reduced total sleep time, reduced sleep efficiency, prolonged sleep latencies, decreased slow-wave sleep, and increased nocturnal awakening. However, because the principal symptoms of restless legs syndrome (RLS) occur during wake, RLS does not require PSG for diagnosis, except where uncertainty exists in the diagnosis. RLS frequently also has a primary motor symptom that is characterized by the occurrence of periodic leg movements in sleep (PLMs). The literature indicates that PLMs are best recorded with PSG from the anterior tibialis muscles. PLMs occur in approximately 80% to 90% of patients who have RLS and support the diagnosis of RLS. In cases where there are frequent PLMs during PSG and a subjective perception of poor sleep in the absence of RLS or sleep-related breathing disorder, periodic limb movement disorder (PLMD) can be diagnosed.

Evidence reviewed by the AASM showed difficulty in diagnosing PLMD without PSG. In a series of 123 patients evaluated for chronic insomnia, a PLMD diagnosis was confirmed in 5 patients and discovered with PSG in another 10 patients. The PLMD scale from a sleep questionnaire had low sensitivity and specificity. Actigraphy, evoked potentials, and blink reflexes have been found to have little diagnostic specificity or utility. PSG-based diagnosis of PLMD correlated best with frequent awakening at night. In
a series of 1171 patients who had PSG at one sleep disorders center, 67 patients (6%) had PLMD as the primary and sole sleep diagnosis. The mean sleep efficiency was 53% and daytime sleepiness was reported by 60% of the cohort. The PLMD patients reported disturbed sleep during a mean of 4 nights per week for a mean of 7 years.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in June 2015 did not identify any ongoing or unpublished trials that would likely influence this policy.

Summary of Evidence

The evidence for polysomnography (PSG) in patients suspected of having a benign parasomnia or restless legs syndrome (RLS) consists of systematic reviews of studies on diagnostic accuracy, case series, and controlled cohort studies. Outcomes of interest are test accuracy, symptoms, functional outcomes, and quality of life. The evidence indicates that typical parasomnias such as sleepwalking or sleep terrors may be diagnosed on the basis of their clinical features and do not require PSG. The movement disorder RLS also does not require PSG, since the principle symptoms of RLS occur during wake as well as during sleep and therefore PSG results are generally not useful. The evidence is sufficient to determine qualitatively that the technology is unlikely to improve the net health outcome.

The evidence for PSG in patients suspected of having narcolepsy, a violent or potentially injurious parasomnia, or periodic limb movement disorder (PLMD) consists of systematic reviews of studies on diagnostic accuracy, case series, and controlled cohort studies. Outcomes of interest are test accuracy, symptoms, functional outcomes, and quality of life. Evidence indicates that PSG followed by the multiple sleep latency test (MSLT) is associated with moderate sensitivity and high specificity for the diagnosis of narcolepsy. For the diagnosis of RBD, combined use of clinical history and PSG to document loss of muscle atonia during REM sleep increases diagnostic accuracy and is considered the gold standard for diagnosis. PSG with electromyography (EMG) of the anterior tibialis is the only method available to diagnose PLMD, but this sleep-related movement disorder is rare and should only be evaluated by PSG if there are no other sleep disorders present. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

In 2005, the American Academy of Sleep Medicine (AASM) published practice parameters for the indications for polysomnography and related procedures. AASM made the following recommendations on the use of PSG for non-respiratory indications:

- PSG and a MSLT performed on the day after the PSG are routinely indicated in the evaluation of suspected narcolepsy. (STANDARD)
Common, uncomplicated, noninjurious parasomnias, such as typical disorders of arousal, nightmares, enuresis, sleeptalking, and bruxism, can usually be diagnosed by clinical evaluation alone. (STANDARD)

PSG is not routinely indicated in cases of typical, uncomplicated, and non-injurious parasomnias when the diagnosis is clearly delineated. (OPTION)

A clinical history, neurologic examination, and a routine EEG obtained while the patients is awake and asleep are often sufficient to establish the diagnosis and permit the appropriate treatment of a sleep related seizure disorder. The need for a routine EEG should be based on clinical judgment and the likelihood that the patient has a sleep relate seizure disorder. (OPTION)

PSG is not routinely indicated for patients with a seizure disorder who have no specific complaints consistent with a sleep disorder. (OPTION)

PSG is indicated when evaluating patients with sleep behaviors suggestive of parasomnias that are unusual or atypical because of the patient’s age at onset; the time, duration or frequency of occurrence of the behavior; or the specifics of the particular motor patterns in question. (GUIDELINE)

PSG is indicated as an OPTION in the following situations:
- Evaluating sleep related behaviors that are violent or otherwise potentially injurious to the patient or others.
- In situations with forensic considerations (eg, if onset follows trauma or if the events themselves have been associated with personal injury).
- When the presumed parasomnia or sleep related seizure disorder does not respond to conventional therapy.

PSG is indicated when a diagnosis of PLMD is considered because of complaints by the patient or an observer of repetitive limb movement during sleep and frequent awakenings, fragmented sleep, difficulty maintaining sleep, or excessive daytime sleepiness. (STANDARD)

Intra-individual night-to-night variability exists in patients with periodic limb movement sleep disorder, and a single study might not be adequate to establish this diagnosis. (OPTION)

PSG is not routinely indicated to diagnose or treat restless legs syndrome, except where uncertainty exists in the diagnosis. (STANDARD)

PSG is not routinely indicated for the diagnosis of circadian rhythm sleep disorders. (STANDARD)

In 2012, AASM published practice parameters for the nonrespiratory indications for polysomnography (PSG) and multiple sleep latency testing in children. The following recommendations for PSG and MSLT were made:

- PSG is indicated for children suspected of having periodic limb movement disorder (PLMD) for diagnosing PLMD. (STANDARD)
- The MSLT, preceded by nocturnal PSG, is indicated in children as part of the evaluation for suspected narcolepsy. (STANDARD)
- Children with frequent NREM parasomnias, epilepsy, or nocturnal enuresis should be clinically screened for the presence of comorbid sleep disorders and polysomnography should be
performed if there is a suspicion for sleep-disordered breathing or periodic limb movement disorder. (GUIDELINE)

- The MSLT, preceded by nocturnal PSG, is indicated in children suspected of having hypersomnia from causes other than narcolepsy to assess excessive sleepiness and to aid in differentiation from narcolepsy. (OPTION)
- The polysomnogram using an expanded EEG montage is indicated in children to confirm the diagnosis of an atypical or potentially injurious parasomnia or differentiate a parasomnia from sleep-related epilepsy (OPTION)
- Polysomnography is indicated in children suspected of having restless legs syndrome (RLS) who require supportive data for diagnosing RLS. (OPTION)

Recommendations against PSG use:

- Polysomnography is not routinely indicated for evaluation of children with sleep-related bruxism. (STANDARD)

AASM issued a 2012 practice parameter on the treatment of restless leg syndrome and periodic limb movement disorder in adults. The practice parameter states many different treatment efficacy measures are used to assess restless leg syndrome (RLS) due to the multifaceted nature of RLS. Measures include both subjective and objective assessments including a number of various subjective scales. The only objective measurements are sleep-related parameters by PSG or actigraphy.

AASM issued a 2010 Best Practice Guide on the treatment of nightmare disorders in adults (classified as a parasomnia). AASM states the overnight PSG is not routinely used to assess nightmare disorder but may be used to exclude other parasomnias or sleep-disordered breathing. PSG may underestimate the incidence and frequency of posttraumatic stress disorder–associated nightmares.

AASM issued a 2010 Best Practice Guide on the treatment of RBD. Minimal diagnostic criteria for RBD are the following:

A) Presence of REM sleep without atonia, defined as sustained or intermittent elevation of submental EMG tone or excessive phasic muscle activity in the limb EMG
B) At least 1 of the following:
   1) Sleep related injurious or potentially injurious disruptive behaviors by history;
   2) Abnormal behaviors documented on polysomnogram (PSG);
C) Absence of epileptiform activity during REM sleep unless RBD can be clearly distinguished from any concurrent R sleep-related seizure disorder
D) Sleep disturbance not better explained by another sleep disorder, medical or neurological disorder, mental disorder, medication use, or substance use disorder

U.S. Preventive Services Task Force Recommendations

Not applicable
Medicare National Coverage

There is no national coverage determination (NCD).

References


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<th>Policy History</th>
<th>Date</th>
<th>Action</th>
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<td>December 2015</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 4, 2015 and is effective January 15, 2016.

Signature on File
Deborah M. Smith, MD, MPH