



## FEP Medical Policy Manual

### FEP 2.01.99 Polysomnography for Non-Respiratory Sleep Disorders

**Effective Policy Date: October 1, 2021**

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**Related Policies:**

2.01.18 - Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

## Polysomnography for Non-Respiratory Sleep Disorders

### Description

#### Description

Polysomnography (PSG) records multiple physiologic parameters relevant to sleep. Video recording may also be performed during PSG to assess parasomnias such as rapid eye movement (REM) sleep behavior 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 rapid eye movement (REM) sleep, some abnormalities of non-REM (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. Most patients with cataplexy have abnormally low levels of hypocretin-1 (orexin-A) in the cerebrospinal fluid.<sup>1</sup> Narcolepsy type 1 (narcolepsy with cataplexy) is defined as excessive daytime sleepiness 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 asleep is typically set at 20 minutes. Patients with narcolepsy often have a mean sleep latency of fewer 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 most patients.

## Parasomnias

Parasomnias are abnormal behavioral, experiential, or physiologic 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. Some, particularly sleepwalking, sleep terrors, and REM sleep behavior disorder (RBD), can cause injury to the patient and others. Parasomnias are classified into parasomnias associated with REM sleep, parasomnias associated with NREM sleep, and other parasomnias.

### Parasomnias Associated With REM Sleep

REM sleep is normally accompanied by muscle atonia, in which there is almost complete paralysis of the body through inhibition of motor neurons. In patients with 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.<sup>2</sup> 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, 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 NREM 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 an incomplete awakening from NREM sleep, usually appears awake with eyes open, is unresponsive to external stimuli, and is amnesic 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 relation to sleep stage and includes sleep-related dissociative disorders, sleep-related enuresis, sleep-related groaning, exploding head syndrome, sleep-related hallucinations, and a sleep-related eating disorder. Diagnosis of these disorders is primarily clinical, although polysomnography (PSG) may be used for differential diagnosis.

- In sleep-related dissociative disorders, behaviors occur during an awakening but the patient is amnesic 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 on falling asleep or during awakening from sleep.
- Sleep-related hallucinations are hallucinations that occur on falling asleep or on 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).

### Restless Legs Syndrome

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.

### Periodic Limb Movement Disorder

Periodic limb movements 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 because periodic limb movements are typically associated with RLS, RBD, or narcolepsy and represent a distinct diagnosis from PLMD.<sup>3</sup>

### Diagnosis

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

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

This review addresses PSG for non-respiratory sleep disorders, which include the hypersomnias (eg, narcolepsy), parasomnias, and movement disorders (eg, RLS, PLMD).

## OBJECTIVE

The objective of this evidence review is to determine whether polysomnography improves the net health outcome for individuals with non-respiratory sleep disorders, which include the hypersomnias (eg, narcolepsy), parasomnias (eg sleep terrors, sleepwalking, rapid eye movement sleep behavior disorder) and movement disorders (eg, restless legs syndrome, periodic limb movement disorder).

## POLICY STATEMENT

Polysomnography (PSG) and a multiple sleep latency test 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 limb movement disorder 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 periodic limb movement disorder is considered **not medically necessary** when there is concurrent untreated obstructive sleep apnea, restless legs syndrome, narcolepsy, or rapid eye movement sleep behavior disorder.

PSG is considered **investigational** for the diagnosis of non-respiratory sleep disorders not meeting the criteria above, including but not limited to nightmare disorder, depression, sleep-related bruxism, or noninjurious disorders of arousal.

## POLICY GUIDELINES

None

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

## FDA REGULATORY STATUS

A large number of PSG devices have been approved since 1986. U.S. Food and Drug Administration product code: OLV.

## RATIONALE

### Summary of Evidence

For individuals who have suspected hypersomnia who receive polysomnography (PSG), the evidence includes a systematic review on diagnostic accuracy. Relevant outcomes are test accuracy, symptoms, functional outcomes, and quality of life (QOL). The evidence has suggested that PSG followed by the multiple sleep latency test is associated with moderate sensitivity and high specificity in support of the diagnosis of narcolepsy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have typical or benign parasomnia who receive PSG, the evidence includes systematic reviews of studies on diagnostic accuracy and cohort studies. Relevant outcomes are test accuracy, symptoms, functional outcomes, and QOL. The evidence has suggested that typical and benign parasomnias (eg, sleepwalking, sleep terrors) may be diagnosed on the basis of their clinical features and do not require PSG. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have violent or potentially injurious parasomnia who receive PSG, the evidence includes systematic reviews of studies on diagnostic accuracy and controlled cohort studies. Relevant outcomes are test accuracy, symptoms, functional outcomes, and QOL. For the diagnosis of REM sleep behavior disorder, the combined use of clinical history and PSG to document the loss of muscle atonia during REM sleep increases diagnostic accuracy and is considered the criterion standard for diagnosis. Diagnostic accuracy is increased with video recording during PSG to assess parasomnias such as REM sleep behavior disorder. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have restless legs syndrome who receive PSG, the evidence includes systematic reviews of studies on diagnostic accuracy and controlled cohort studies. Relevant outcomes are test accuracy, symptoms, functional outcomes, and QOL. Restless legs syndrome does not require PSG because the syndrome is a sensorimotor disorder, the symptoms of which occur predominantly when awake; therefore, PSG results are generally not useful. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have periodic limb movement disorder who receive PSG, the evidence includes a systematic review. Relevant outcomes are test accuracy, symptoms, functional outcomes, and QOL. PSG with electromyography of the anterior tibialis is the only method available to diagnose periodic limb movement disorder, but this sleep-related movement disorder is rare and should only be evaluated using PSG in the absence of symptoms of other disorders. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

The American Academy of Sleep Medicine (AASM; 2005) published practice parameters for polysomnography (PSG) and related procedures.<sup>1</sup> AASM made the following recommendations on the use of PSG for nonrespiratory indications (see Table 1).

**Table 1. Practice Parameters on PSG for Nonrespiratory Indications**

Recommendation	Grade
Polysomnography and a multiple sleep latency test performed on the day after the polysomnographic evaluation are routinely indicated in the evaluation of suspected narcolepsy	Standard
Common, uncomplicated, noninjurious parasomnias, such as typical disorders of arousal, nightmares, enuresis, sleepwalking, and bruxism, can usually be diagnosed by clinical evaluation alone	Standard

Polysomnography is not routinely indicated in cases of typical, uncomplicated, and noninjurious parasomnias when the diagnosis is clearly delineated	Option
A clinical history, neurologic examination, and a routine EEG obtained while the patients are 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-related seizure disorder.	Option
Polysomnography is not routinely indicated for patients with a seizure disorder who have no specific complaints consistent with a sleep disorder	Option
Polysomnography 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
Polysomnography ... is indicated in evaluating sleep-related behaviors that are violent or otherwise potentially injurious to the patient or others	Option
Polysomnography may be indicated in situations with forensic considerations (e.g., if onset follows trauma or if the events themselves have been associated with personal injury)	Option
Polysomnography may be indicated when the presumed parasomnia or sleep-related seizure disorder does not respond to conventional therapy	Option
Polysomnography is indicated when a diagnosis of periodic limb movement disorder 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
Polysomnography is not routinely indicated to diagnose or treat restless legs syndrome, except where uncertainty exists in the diagnosis	Standard
Polysomnography is not routinely indicated for the diagnosis of circadian rhythm sleep disorders	Standard

EEG: electroencephalography.

The AASM (2017) updated its practice parameters on PSG.<sup>9</sup> Most recommendations were unchanged from the 2005 guideline. For narcolepsy, the guidelines note that a clinical history, sleep diaries, PSG, and a multiple sleep latency test are key items in the evaluation of the disorder.

The AASM (2012) published practice parameters on nonrespiratory indications for PSG and multiple sleep latency testing in children.<sup>4</sup> Table 2 lists recommendations for PSG and multiple sleep latency testing.

**Table 2. Practice Parameters on PSG for Nonrespiratory Indications in Children**

Recommendation	Grade
PSG is indicated for children suspected of having 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	Option

causes other than narcolepsy to assess excessive sleepiness and to aid in differentiation from narcolepsy	
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 when the initial clinical evaluation and standard EEG are inconclusive	Option
Polysomnography is indicated in children suspected of having RLS who require supportive data for diagnosing RLS	Option
Polysomnography is not routinely indicated for evaluation of children with sleep-related bruxism	Standard

EEG: electroencephalography; MSLT: multiple sleep latency test; NREM: non-rapid eye movement; PLMD: periodic limb movement disorder; PSG: polysomnography; RLS: restless legs syndrome.

The AASM (2012) issued a practice parameter on the treatment of restless legs syndrome and periodic limb movement disorder in adults.<sup>3</sup> The practice parameter noted different treatment efficacy measures are used to assess restless legs syndrome due to its multifaceted nature. Measures included a number of subjective scales; the only objective measurements were sleep-related parameters by PSG or actigraphy.

The AASM (2010) issued best practice guide on the treatment of nightmare disorders in adults (classified as a parasomnia).<sup>10</sup> The AASM stated that 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.

The AASM (2010) issued best practice guide on the treatment of rapid eye movement (REM) sleep behavior disorder (RBD).<sup>2</sup> Minimal diagnostic criteria for RBD included:

1. Presence of R[EM] sleep without atonia, defined as sustained or intermittent elevation of submental EMG [electromyographic] tone or excessive phasic muscle activity in the limb EMG [electromyography] ...;
2. At least 1 of the following:
  1. Sleep-related injurious or potentially injurious disruptive behaviors by history;
  2. Abnormal R[EM] behaviors documented on polysomnogram (PSG);
3. Absence of epileptiform activity during R[EM] sleep unless RBD can be clearly distinguished from any concurrent R[EM] sleep-related seizure disorder;
4. 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

## REFERENCES

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6. Drakatos P, Marples L, Muza R, et al. Video polysomnographic findings in non-rapid eye movement parasomnia. *J Sleep Res*. Apr 2019; 28(2): e12772. PMID 30295353
7. Neikrug AB, Ancoli-Israel S. Diagnostic tools for REM sleep behavior disorder. *Sleep Med Rev*. Oct 2012; 16(5): 415-29. PMID 22169258
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9. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. Mar 15 2017; 13(3): 479-504. PMID 28162150
10. Aurora RN, Zak RS, Auerbach SH, et al. Best practice guide for the treatment of nightmare disorder in adults. *J Clin Sleep Med*. Aug 15 2010; 6(4): 389-401. PMID 20726290

## **POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<b>Date</b>	<b>Action</b>	<b>Description</b>
December 2015	New policy	
December 2016	Replace policy	Policy statements unchanged.
December 2017	Replace policy	Policy updated with literature review through July 21, 2017; no references added. Policy statements unchanged.
September 2018	Replace policy	Policy updated with literature review through April 30, 2018; reference 8 added. Policy statements unchanged.
September 2019	Replace policy	Policy updated with literature review through April 1, 2019; no references added. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through July 26, 2020; references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through April 24, 2021; no references added. Policy statements unchanged.

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