

(20199)

Medical Benefit		Effective Date: 09/01/19	Next Review Date: 07/21
Preauthorization	Yes	Review Dates: 07/19, 07/20	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

RELATED PROTOCOL

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Populations	Interventions	Comparators	Outcomes
Individuals: • With suspected hypersomnia	Interventions of interest are: • Polysomnography	Comparators of interest are: • Clinical diagnosis alone	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Quality of life
Individuals: • With typical or benign parasomnia	Interventions of interest are: • Polysomnography	Comparators of interest are: • Clinical diagnosis alone	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Quality of life
Individuals: • With violent or potentially injurious parasomnia	Interventions of interest are: • Polysomnography	Comparators of interest are: • Clinical diagnosis alone	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Quality of life
Individuals: • With restless legs syndrome	Interventions of interest are: • Polysomnography	Comparators of interest are: • Clinical diagnosis alone	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Quality of life
Individuals: • With periodic limb movement disorder	Interventions of interest are: • Polysomnography	Comparators of interest are: • Clinical diagnosis alone	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Quality of life

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.

SUMMARY OF EVIDENCE

HYPERMOMNIA

For individuals who have suspected hypersomnia who receive PSG, the evidence includes a systematic review on diagnostic accuracy. The 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 a meaningful improvement in the net health outcome.

PARASOMNIAS

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

SLEEP-RELATED MOVEMENT DISORDERS

For individuals who have restless legs syndrome who receive PSG, the evidence includes systematic reviews of studies on diagnostic accuracy and controlled cohort studies. The 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 sufficient to determine that the technology is unlikely to improve the net health outcome.

For individuals who have periodic limb movement disorder who receive PSG, the evidence includes a systematic review. The 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 a meaningful improvement in the net health outcome.

POLICY

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 non-injurious disorders of arousal.

BACKGROUND

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.¹ 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 two 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 five minutes and two 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 and family functioning. 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.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, 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 five 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.³

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 protocol addresses PSG for non-respiratory sleep disorders, which include the hypersomnias (e.g., narcolepsy), parasomnias, and movement disorders (e.g., RLS, PLMD).

REGULATORY STATUS

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

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

REFERENCES

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

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