Polysomnography for Non-Respiratory Sleep Disorders

Policy # 00481
Original Effective Date: 11/16/2015
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome is addressed separately in medical policy 00328.

Note: Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome is addressed separately in medical policy 00329.

Note: Actigraphy is addressed separately in medical policy 00330.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider polysomnography (PSG) and a multiple sleep latency test performed on the day after the PSG in the evaluation of suspected narcolepsy or idiopathic hypersomnia to be eligible for coverage.

Based on review of available data, the Company may consider polysomnography (PSG) when evaluating patients with parasomnias when there is a history of sleep related injurious or potentially injurious disruptive behaviors to be eligible for coverage.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider polysomnography (PSG) for a diagnosis of periodic limb movement disorder (PLMD) to be eligible for coverage when there is:

Patient Selection Criteria
Coverage eligibility will be considered when the following criteria is met:

- 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
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- Difficulty maintaining sleep; OR
- Excessive daytime sleepiness

When Services Are Considered Not Medically Necessary
Based on review on available data, the Company considers the use of polysomnography (PSG) for the diagnosis of PLMD when there is concurrent untreated obstructive sleep apnea, restless legs syndrome, narcolepsy, or REM sleep behavior disorder to be not medically necessary.**

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers polysomnography (PSG) 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 to be investigational.*

The use of polysomnography (PSG) when patient selection criteria are not met is considered to be investigational.*

Background/Overview
Polysomnography 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 to assess muscle tone and detect rapid eye movement (REM) sleep,
- Respiratory effort, airflow, blood oxygen saturation (oximetry) and electrocardiography to assess apneic events,
- Anterior tibialis EMG to assess periodic limb movements (PLMs) during sleep, and
- Video recording to detect any unusual behavior.

This policy addresses PSG for non–respiratory sleep disorders, which include the hypersomnias (eg, narcolepsy), parasomnias, and movement disorders (eg, restless legs syndrome [RLS], PLMD).

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 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. 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.
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(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 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 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, 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 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. 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 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.
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- 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 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 RLS and PLMD.

Restless Legs Syndrome
Restless legs syndrome 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 as PLMS are typically associated with RLS, RBD, or narcolepsy and represent a distinct diagnosis from PLMD.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
A large number of polysomnography devices have been approved since 1986. U.S. FDA product code: OLV.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source
Hypersomnias
Evidence reviewed by AASM included a data review of 1602 patients, of which 176 patients had narcolepsy and 1426 had other sleep disorders. In patients with clinical narcolepsy, 2 or more sleep-onset REM periods
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(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 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 (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 PSG is used to rule out other potential causes of sleepiness followed by an 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 1 or more of the other symptoms, the laboratory criteria are required to establish the diagnosis of narcolepsy.

Parasomnias
Evidence reviewed by 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 on 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 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 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 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 4 cardinal diagnostic features of 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.
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Evidence reviewed by AASM included a case-control study which found that compared with 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 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 PLMs in sleep. 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, PLMD can be diagnosed.

Evidence reviewed by 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 1 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 review.

Summary of Evidence
The evidence for PSG in patients suspected of having a benign parasomnia or RLS includes systematic reviews of studies on diagnostic accuracy, case series, and controlled cohort studies. Relevant outcomes are test accuracy, symptoms, functional outcomes, and quality of life. The evidence indicates that typical and benign parasomnias such as sleepwalking or sleep terrors may be diagnosed on the basis of their clinical features and do not require PSG. RLS also does not require PSG because RLS is a sensorimotor disorder, the symptoms of which occur predominantly during wake. 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 PLMD includes systematic reviews of studies on diagnostic accuracy, case series, and controlled cohort studies. Relevant outcomes are test accuracy, symptoms, functional outcomes, and quality of life. Evidence indicates that PSG followed by the MSLT is associated with moderate sensitivity and high specificity in support of 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 criterion standard for diagnosis. PSG with EMG of the anterior tibialis is the only method available to diagnose PLMD, but this sleep-related movement disorder is rare and should only
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be evaluated by PSG in the absence of symptoms of other disorders. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

References

Policy History
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10/29/2015 Medical Policy Committee review
11/16/2015 Medical Policy Implementation Committee approval. New policy.
10/01/2016 Coding update
11/03/2016 Medical Policy Committee review
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
Next Scheduled Review Date:  11/2017

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2015 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);

2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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