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2.01.99	Polysomnography for Non-Respiratory Sleep Disorders		
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Section:	2.0 Medicine	Page:	Page 1 of 18

Policy Statement

- I. 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.
- II. PSG may be **medically necessary** when evaluating individuals with parasomnias when there is a history of sleep-related injurious or potentially injurious disruptive behaviors.
- III. PSG may be **medically necessary** when a diagnosis of periodic limb movement disorder is considered when **all** of the following are met:
 - A. A complaint of repetitive limb movement during sleep by the individual or an observer
 - B. No other concurrent sleep disorder
 - C. At least **one** of the following is present:
 - 1. Frequent awakenings
 - 2. Fragmented sleep
 - 3. Difficulty maintaining sleep
 - 4. Excessive daytime sleepiness
- IV. PSG for the diagnosis of periodic limb movement disorder is considered **investigational** when there is concurrent untreated obstructive sleep apnea, restless legs syndrome, narcolepsy, or rapid eye movement sleep behavior disorder.
- V. PSG is considered **investigational** for the diagnosis of non-respiratory sleep disorders not meeting the criteria above, including but not limited to **any** of the following:
 - A. Depression
 - B. Nightmare disorder
 - C. Noninjurious disorders of arousal
 - D. Sleep-related bruxism

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

The following CPT codes are specific to this testing:

- **95782**: Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
- **95783**: Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
- **95805**: Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
- **95808**: Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
- **95810**: Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist

2.01.99 Polysomnography for Non-Respiratory Sleep Disorders Page 2 of 18

• **95811**: Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist

Description

Polysomnography records multiple physiologic parameters relevant to sleep. Video recording may also be performed during PSG to assess parasomnias such as rapid eye movement sleep behavior disorder.

Related Policies

• Diagnosis of Obstructive Sleep Apnea Syndrome

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

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

Rationale

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). During 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 alseep 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

Normally, REM sleep is 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 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 relation to sleep stage and includes sleeprelated 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 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 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 review addresses PSG for non-respiratory sleep disorders, which include the hypersomnias (e.g., narcolepsy), parasomnias, and movement disorders (e.g., RLS, PLMD).

Literature Review

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

2.01.99 Polysomnography for Non-Respiratory Sleep Disorders

Page 5 of 18

Hypersomnia

Clinical Context and Test Purpose

The purpose of polysomnography (PSG) is to provide a diagnostic option that is an alternative to or an improvement on existing tests in individuals with suspected hypersomnia.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with suspected hypersomnia.

Interventions

The test being considered is PSG. 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 (RBD).

Comparators

Comparators of interest include clinical diagnosis alone.

Outcomes

The general outcomes of interest are test accuracy, symptoms, functional outcomes, and quality of life (QOL). The classic symptoms include hypersomnolence, cataplexy, sleep paralysis, and hypnagogic (onset of sleep) hallucinations as well as related findings on PSG.

Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristic, area under receiver operating characteristic, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Systematic Reviews

Evidence reviewed by Chesson et al (1997) for the American Academy of Sleep Medicine (AASM) included data on 1602 patients, of whom 176 patients had narcolepsy, and 1426 had other sleep disorders.^{4,} However, 7% of patients with obstructive sleep apnea and 5% of patients with other sleep disorders had 2 sleep-onset REMs on a multiple sleep latency test (MSLT), leading to a low predictive value for narcolepsy. No data were found that validated the maintenance of wakefulness test (which measures a 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 criterion standard of nocturnal PSG with an MSLT on the day following the diagnosis of narcolepsy. An evidence review by Kushida et al (2005), also for AASM, found that the presence of 2 or more early sleep-onset latency episodes was associated with a sensitivity of 78% and specificity of 93% for the diagnosis of narcolepsy.¹,

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Based on the evidence reviewed, the updated AASM (2005) guidelines indicated that PSG should be 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 are one or more of the other symptoms, the laboratory criteria are required to establish the diagnosis of narcolepsy.

Section Summary: Hypersomnia

Evidence from a systematic review has indicated that, in patients suspected of having hypersomnia, nocturnal PSG should be used to rule out other sleep disorders that may cause daytime sleepiness. After excluding other sleep disorders with nocturnal PSG or a portable sleep study, short sleep latency in an MSLT has high specificity for the diagnosis of hypersomnia.

Typical or Benign Parasomnia

Clinical Context and Test Purpose

The purpose of PSG is to provide a diagnostic option that is an alternative to or an improvement on existing tests in individuals with typical or benign parasomnia.

The following PICO was used to select literature to inform this review.

Populations

The population of interest is individuals with typical or benign parasomnias.

Interventions

The test being considered is PSG. PSG records multiple physiologic parameters relevant to sleep. Video recording may also be performed during PSG to assess parasomnias such as RBD.

Comparators

Comparators of interest include clinical diagnosis alone.

Outcomes

The general outcomes of interest are test accuracy, symptoms, functional outcomes, and QOL as well as related findings on PSG.

Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.

- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristic, area under receiver operating characteristic, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Systematic Reviews

Evidence reviewed by Chesson et al (1997) for AASM 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 historical clinical features.^{4,} This conclusion was based on very consistent descriptive literature (case series and cohort studies).

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs. No relevant RCTs were identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Section Summary: Typical or Benign Parasomnia

The evidence on the diagnosis of typical or benign parasomnias includes a systematic review of case series and cohort studies. This evidence has shown that PSG does not provide additional diagnostic information beyond what can be obtained from historical clinical features.

Violent or Potentially Injurious Parasomnia

Clinical Context and Test Purpose

The purpose of PSG is to provide a diagnostic option that is an alternative to or an improvement on existing tests in individuals with violent or potentially injurious parasomnia.

The following PICO was used to select literature to inform this review.

Populations

The population of interest is individuals with violent or potentially injurious parasomnia.

Interventions

The test being considered is PSG. PSG records multiple physiologic parameters relevant to sleep. Video recording may also be performed during PSG to assess parasomnias such as RBD.

2.01.99 Polysomnography for Non-Respiratory Sleep Disorders

Page 8 of 18

Comparators

Comparators of interest include clinical diagnosis alone.

Outcomes

The general outcomes of interest are test accuracy, symptoms, functional outcomes, and QOL as well as related findings on PSG.

Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are • described.
- The test is compared with a credible reference standard. •
- If the test is intended to replace or be an adjunct to an existing test; it should also be • compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely • report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristic, area under receiver operating characteristic, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Systematic Reviews

When events are not typical of benign partial arousals and where other diagnoses, prognoses, and interventions should be considered, PSG was recommended by Chesson et al (1997) and supported by AASM. This evidence review included only 3 articles on disorders of arousal and 2 articles for RBD that included comparison data for normal controls.^{4,} Most articles supporting the utility of PSG were limited by biases inherent in uncontrolled clinical reports. Evidence reviewed by Aurora et al (2010) for an AASM best practice guideline indicated 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%.^{2,} 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 a sustained or intermittent elevation of submental electromyogram tone or excessive phasic muscle activity in the limb electromyogram.^{2,} Two clinical series with over 100 patients each with various parasomnias found that PSG had an overall diagnostic yield in 65% and 91% of cases. Results from a more recent retrospective observational study of video PSG were similar, finding that among a cohort of 516 patients with suspected non-REM parasomnias, 65% had video PSG findings consistent with a clinical diagnosis of parasomnia.^{5,} In a systematic review assessing the diagnosis of RBD, Neikrug and Ancoli-Israel (2012) reported that diagnostic accuracy increases when combining the use of clinical history and video PSG to document the intermittent or sustained loss of muscle tone or the actual observation of RBD occurrences.^{6,}

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

2.01.99 Polysomnography for Non-Respiratory Sleep Disorders Page 9 of 18

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs. No relevant RCTs were identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

The need for PSG was also indicated in a review of parasomnias by Goldstein (2011), who concluded that, although RBD is the only parasomnia requiring PSG for diagnosis, PSG may be needed to rule out another sleep pathology, such as sleep-disordered breathing or periodic limb movements of sleep, that might cause a parasomnia.^{7,}

Section Summary: Violent or Potentially Injurious Parasomnia

The evidence on the use of PSG for diagnosing violent or potentially injurious parasomnia includes many case series and a systematic review of nonrandomized comparative studies. The large series showed a high diagnostic yield for video PSG in cases with a violent or potentially injurious parasomnia based on clinical history. Clinical utility is based on the importance of excluding other sleep disorders and appropriate interventions in patients who exhibit REM sleep without atonia.

Restless Legs Syndrome

Clinical Context and Test Purpose

The purpose of PSG is to provide a diagnostic option that is an alternative to or an improvement on existing tests in individuals with restless legs syndrome (RLS).

The following PICO was used to select literature to inform this review.

Populations

The population of interest is individuals with RLS.

Interventions

The test being considered is PSG. PSG records multiple physiologic parameters relevant to sleep. Video recording may also be performed during PSG to assess parasomnias such as RBD.

Comparators

Comparators of interest include clinical diagnosis alone.

Outcomes

The general outcomes of interest are test accuracy, symptoms, functional outcomes, and QOL as well as the results of the PSG.

Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristic, area under receiver operating characteristic, c-statistic, likelihood ratios) may be included but are less informative.

2.01.99 Polysomnography for Non-Respiratory Sleep Disorders

Page 10 of 18

• Studies should also report reclassification of diagnostic or risk category.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Systematic Reviews

The 4 cardinal diagnostic features of RLS include (1) an urge to move the limbs (this is usually associated with paresthesias or dysesthesias), (2) symptoms that start or worsen with rest, (3) at least partial relief of symptoms with physical activity, and (4) worsening of symptoms in the evening or at night.^{3,} Evidence reviewed by the AASM included a case-control study that found RLS patients when compared with controls, had reduced total sleep time, reduced sleep efficiency, prolonged sleep latencies, decreased slow-wave sleep, and increased nocturnal awakening.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs. No relevant RCTs were identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the principal symptoms of RLS occur during wake, RLS does not require PSG for diagnosis, except where uncertainty exists in the diagnosis.^{14,} RLS frequently also has a primary motor symptom that is characterized by the occurrence of periodic limb movements during sleep. Periodic limb movements occur in 80% to 90% of patients who have RLS and support the diagnosis of RLS.

Section Summary: Restless Legs Syndrome

A case-control study has shown that RLS impairs PSG measures of sleep; however, the principal symptoms of RLS occur during wake and, therefore, the disorder does not require PSG for diagnosis.

Periodic Limb Movement Disorder

Clinical Context and Test Purpose

The purpose of PSG is to provide a diagnostic option that is an alternative to or an improvement on existing tests in individuals with periodic limb movement disorder (PLMD).

The following PICO was used to select literature to inform this review.

Populations

The population of interest is individuals with PLMD.

Interventions

The test being considered is PSG. PSG records multiple physiologic parameters relevant to sleep. Video recording may also be performed during PSG to assess parasomnias such as RBD.

Comparators

Comparators of interest include clinical diagnosis alone.

2.01.99 Polysomnography for Non-Respiratory Sleep Disorders Page 11 of 18

Outcomes

The general outcomes of interest are test accuracy, symptoms, functional outcomes, and QOL as well as results of PSG.

Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristic, area under receiver operating characteristic, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Systematic Reviews

The evidence reviewed by Chesson et al (1997) for AASM suggested difficulty in diagnosing PLMD without PSG.^{4,} 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 (6%) patients 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.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs. No relevant RCTs were identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

PLMD can be diagnosed in the following cases: during PSG; during a subjective perception of poor sleep in the absence of RLS; or during a sleep-related breathing disorder.^{3,}

2.01.99 Polysomnography for Non-Respiratory Sleep Disorders Page 12 of 18

Section Summary: Periodic Limb Movement Disorder

The evidence for the use of PSG for diagnosing PLMD includes a systematic review that concluded the diagnosis of PLMD is difficult without PSG. The review found low diagnostic accuracy of a sleep questionnaire or actigraphy, while a PSG-based diagnosis of PLMD correlated best with awakening at night.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.

American Academy of Sleep Medicine

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

Table 1. Practice Parameters on Polysomnography for Nonrespiratory Indications

Table 1. Fractice Fuldimeters on Folyson nography for Nonrespiratory indications	
Recommendation	Grade
PSG 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, sleeptalking, and bruxism, can usually be diagnosed by clinical evaluation alone.	Standard
PSG 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
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 in evaluating sleep-related behaviors that are violent or otherwise potentially injurious to the patient or others.	Option
PSG 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
PSG may be indicated when the presumed parasomnia or sleep-related seizure disorder does not respond to conventional therapy.	Option
PSG 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
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

The AASM (2012) published practice parameters on nonrespiratory indications for PSG and multiple sleep latency testing in children.^{8,} Table 2 lists recommendations for PSG and multiple sleep latency testing.

Table 2. Practice Parameters on Polysomnography 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 PSG should be performed if there is a suspicion for sleep-disordered breathing or PLMD.	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 when the initial clinical evaluation and standard EEG are inconclusive.	Option	
PSG is indicated in children suspected of having RLS who require supportive data for diagnosing RLS.	Option	
PSG 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.^{3,} 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 a position paper on the treatment of nightmare disorders in adults (classified as a parasomnia).^{9,} 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. In 2018, the AASM updated its position paper; , however, there was no mention of PSG.^{10,}

The AASM (2023) issued best practice guide on the treatment of rapid eye movement (REM) sleep behavior disorder (RBD).^{11,} All forms of RBD (primary, secondary, and drug-induced) are defined in the guideline as emergence of dream enactment with a documented elevation in REM sleep motor tone on PSG. In patients with secondary RBG, these findings occur in the context of an underlying disorder, and in patients with drug-induced RBD, they occur after starting or increasing the dose of a serotonergic medication. PSG was mentioned in the context of treatment selection, since pramipexole was noted to be most effective among patients with periodic limb movements seen on PSG.

International RBD Study Group

The Neurophysiology Working Group of the International RBD Study Group (IRBDSG) (2022) issued guidelines on video PSG (v-PSG) procedures for the diagnosis of RBD.^{12,} The working group states that v-PSG "is mandatory to diagnose RBD, following technical requirements for sleep recording described in Technical Requirements for v-PSG Recording section and scoring REM sleep as described in REM Sleep Scoring section and in the AASM manual". The group also states that v-PSG is mandatory to identify prodromal RBD.

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.

Ongoing and Unpublished Clinical Trials

A search of <u>ClinicalTrials.gov</u> in April 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
 - o Reason for polysomnography
 - o Symptoms of sleep disorder
 - Prior treatment(s) including duration and response(s)

Post Service (in addition to the above, please include the following):

- Polysomnography report
- Multiple sleep latency test report, if applicable

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Туре	Code	Description
	95782	Polysomnography; younger than 6 years, sleep staging with 4 or more
		additional parameters of sleep, attended by a technologist
	95783 95805	Polysomnography; younger than 6 years, sleep staging with 4 or more
		additional parameters of sleep, with initiation of continuous positive
		airway pressure therapy or bi-level ventilation, attended by a
		technologist
		Multiple sleep latency or maintenance of wakefulness testing, recording,
CPT [®]		analysis and interpretation of physiological measurements of sleep
		during multiple trials to assess sleepiness
	95808	Polysomnography; any age, sleep staging with 1-3 additional
	93606	parameters of sleep, attended by a technologist
-	95810	Polysomnography; age 6 years or older, sleep staging with 4 or more
		additional parameters of sleep, attended by a technologist
	95811	Polysomnography; age 6 years or older, sleep staging with 4 or more
		additional parameters of sleep, with initiation of continuous positive
		airway pressure therapy or bilevel ventilation, attended by a
		technologist
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	
02/01/2017	BCBSA Medical Policy adoption	
11/01/2017	Policy revision without position change	
07/01/2018	Policy statement clarification	
08/01/2018	Policy revision without position change	
11/01/2019	Policy revision without position change	
08/01/2023	Policy reactivated. Previously archived from 04/01/2020 to 07/31/2023.	

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent

2.01.99 Polysomnography for Non-Respiratory Sleep Disorders Page 16 of 18

with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at <u>www.blueshieldca.com/provider</u>.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: <u>MedPolicy@blueshieldca.com</u>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT		
BEFORE	AFTER	
	Blue font: Verbiage Changes/Additions	
Reactivated Policy	Polysomnography for Non-Respiratory Sleep Disorders 2.01.99	
Policy Statement: N/A	 Policy Statement: 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. 	
	II. PSG may be medically necessary when evaluating individuals with parasomnias when there is a history of sleep-related injurious or potentially injurious disruptive behaviors.	
	 III. PSG may be medically necessary when a diagnosis of periodic limb movement disorder is considered when all of the following are met: A. A complaint of repetitive limb movement during sleep by the individual or an observer B. No other concurrent sleep disorder C. At least one of the following is present: Frequent awakenings Fragmented sleep Difficulty maintaining sleep Excessive daytime sleepiness 	
	IV. PSG for the diagnosis of periodic limb movement disorder is considered investigational when there is concurrent untreated obstructive sleep apnea, restless legs syndrome, narcolepsy, or rapid eye movement sleep behavior disorder.	
	 V. PSG is considered investigational for the diagnosis of non-respiratory sleep disorders not meeting the criteria above, including but not limited to any of the following: A. Depression B. Nightmare disorder C. Noninjurious disorders of arousal 	

2.01.99 Polysomnography for Non-Respiratory Sleep Disorders Page 18 of 18

POLICY STATEMENT		
BEFORE	AFTER <u>Blue font</u> : Verbiage Changes/Additions	
	D. Sleep-related bruxism	