Contractor Information |LCD Information | Coding Information |General Information

FIRST COAST SERVICE OPTIONS, INC.
WHEN EXPERIENCE COUNTS & QUALITY MATTERS

Contractor Information

Contractor Name

First Coast Service Options, Inc.

Contractor Number

09102

Contractor Type

MAC - Part B

LCD Information

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LCD ID Number

L29949

LCD Title

Polysomnography and Sleep Testing

Contractor's Determination Number

95805

AMA CPT / ADA CDT Copyright Statement

CMS National Coverage Policy

Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 6, Section 50

CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 70

CMS Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 240.4

CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 4, provides information on the Outpatient Prospective Payment System

CMS Decision Memo for Continuous Positive Airway Pressure Therapy for Obstructive Sleep Apnea (CAG-00093R2)

CMS Decision Memo for Sleep Testing for Obstructive Sleep Apnea (CAG-00405N)

CMS Transmittal 103, Change Request 6534

Primary Geographic Jurisdiction

Florida

Oversight Region

Region IV

Original Determination Effective Date

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Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Abstract

About 40 million people in the United States suffer from sleep problems every year. Not getting enough sleep for a long time can cause health problems. Many sleep disorders can be managed by primary care physicians; however, when abnormal sleep patterns are not easily explainable and further evaluation is necessary, expert opinion and sleep studies may be needed.

Sleep consists of two distinct states: rapid eye movement (REM), and non-rapid eye movement (NREM). REM sleep is when we dream. NREM sleep is further divided into three stages. Stages one and two are referred to as light sleep and stage three as deep sleep. The first sleep cycles each night contain relatively short REM periods and long periods of deep sleep. As the night progresses, REM sleep periods increase in length while deep sleep decreases. By morning, people spend nearly all their sleep time in stages one, two, and REM.

Polysomnography (PSG) refers to the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep furnished in a sleep laboratory facility that includes physician review, interpretation and report. A technologist is physically present to supervise the recording during sleep time and has the ability to intervene, if needed. The studies are performed to diagnose a variety of sleep disorders and to evaluate a patient's response to therapies such as continuous positive airway pressure (CPAP). PSG is distinguished from sleep studies by the inclusion of sleep staging, which requires items 1 through 3 listed below.

PSG is defined to minimally include, but is not limited to, the following:

1. At minimum, a 3 lead electroencephalogram (EEG) to measure global neural encephalographic activity using electrodes placed on the scalp

2. Electrooculogram (EOG) to measure eye movements using electrodes placed near the outer canthus of each eye

3. A submental electromyogram (EMG) to measure submental electromyographic activity using electrodes placed over the mentalis, submentalis muscle, and/or masseter regions

4. Rhythm electrocardiogram (ECG)

5. Nasal and/or oral airflow via both thermistor and nasal pressure sensor

6. Respiratory effort by chest-wall and abdominal movement measured using respiratory inductive plethysmography, endoesophageal pressure or by intercostal EMG

7. Gas exchange (oxygen saturation (SpO2)) by oximetry or transcutaneous monitoring

8. Bilateral anterior tibialis muscle activity, motor activity-movement using EMG

9. Body positions by directly applied sensors or by direct observation

PSG and other sleep test monitoring devices are generally classified based on the number of biologic sensors applied and physiologic parameters recorded.

· ***Type I PSG*** *is covered when used to aid the diagnosis of obstructive sleep apnea (OSA) in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.* Type I devices are capable of recordings of all of the physiologic parameters and signals defined for PSG. The recording is furnished in a sleep laboratory facility in which a technologist is physically present to supervise the recording during sleep time and has the ability to intervene if needed. Minimal requirements include recording of EEG, EOG, chin EMG, anterior tibialis EMG, ECG, airflow, respiratory effort and oxygen saturation. Body position must be documented or objectively measured. Trained personnel must be in constant attendance and able to intervene.

· ***A Type II*** *sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.* Type II devices are portable devices that may measure the same channels as type I testing, except that a heart-rate monitor can replace the ECG. This device has a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, respiratory effort, and oxygen saturation – this type of device monitors sleep staging). A sleep technician is not necessarily in constant attendance in Type II studies but is needed for preparation.

· ***A Type III*** *sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.* Type III devices monitor and record a minimum of 4 channels and must record ventilation or airflow, heart rate or ECG, and oxygen saturation. A sleep technician is not necessarily in constant attendance in Type III studies but is needed for preparation.

· ***A Type IV*** *sleep testing device measuring three or more channels, one of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.* Type IV devices must include airflow as one of the required 3 channels. Other measurements may include oximetry and heart rate. A sleep technician is not necessarily in constant attendance in Type IV studies but is needed for preparation.

· *A sleep testing device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.* A sleep technician is not necessarily in constant attendance in such studies but is needed in preparation.

Multiple sleep latency testing (MSLT) involves four or five 20-minute nap opportunities offered at 2-hour intervals. MSLT objectively assesses sleep tendency by measuring the number of minutes it takes the patient to fall asleep. Conversely, the maintenance of wakefulness test (MWT) requires the patient to try to stay awake. MSLT is the better test for demonstration of sleep-onset REM periods, a determination that is important in establishing the diagnosis of narcolepsy. To insure validity, proper interpretation of the MSLT can only be made following a polysomnography performed on the preceding night.

Indications of Coverage:

Normally, sleep studies and PSG for sleep disorders are performed in sleep centers or laboratories. However, the diagnosis of OSA for coverage of CPAP may also be established by home sleep testing (HST) as indicated under number 2 (Sleep Apnea) below.

Sleep disorder clinics (centers and laboratories) *are facilities in which certain conditions are diagnosed through the study of sleep. Such clinics* (centers and laboratories) *are for diagnosis, therapy, and research. Sleep disorder clinics* (centers and laboratories) *may provide some diagnostic or therapeutic services, which are covered under Medicare. These clinics* (centers and laboratories) *may be affiliated either with a hospital or a freestanding facility. Whether a clinic* (sleep center or laboratory) *is hospital-affiliated or freestanding, coverage for diagnostic services under some circumstances is covered under provisions of the law different from those for coverage of therapeutic services.*

Diagnostic testing is covered only if the patient has the symptoms or complaints of one of the conditions listed below. Most

of the patients who undergo the diagnostic testing are not considered inpatients, although they may come to the facility in the evening for testing and then leave after testing is over. If HST is used, they may be tested in the home environment after application of the sensors and receiving education regarding a monitoring device from the technical, professional, or appropriately trained staff of the sleep center or laboratory. The overnight stay in the sleep center or laboratory is considered an integral part of PSG, MSLT, and MWT but not for HST.

When sleep studies are performed in sleep disorder centers or laboratories or when HST is used, the following criteria must be met:

· *The clinic* (sleep center or laboratory) *is either affiliated with a hospital or is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder clinics (centers and laboratories) may be covered even in the absence of direct supervision by a physician;*

· *Patients are referred to the sleep disorder clinic by their attending physicians, and the clinic (center or laboratory) maintains a record of the attending physician's orders; and*

· *The need for diagnostic testing is confirmed by medical evidence, e.g., physician examinations and laboratory tests.* Prior to any sleep testing, the patient must have a face-to-face clinical evaluation by the treating physician which must at minimum include:

1. Sleep history and symptoms including, but not limited to, snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches; and,

2. Epworth sleepiness scale; and,

3. Physical examination that documents body mass index, neck circumference and a focused cardiopulmonary and upper airway evaluation.

Accreditation

In order to perform the technical component (TC) of PSG and sleep testing (including HST), the following must be met:

· The sleep center or laboratory must maintain documentation on file that indicates it is accredited by the American Academy of Sleep Medicine (AASM) or that it is accredited as a sleep laboratory by the Joint Commission. If the Joint Commission survey of the general hospital accreditation includes the hospital-based sleep lab, an additional accreditation is not needed. This documentation must be available to Medicare on request. The AASM or Joint Commission accreditation applies to the hospital and freestanding facilities (including sleep clinics that are part of a physician's office, Independent Diagnostic Testing Facility (IDTF), and all other non-hospital-based facilities where sleep studies are performed.

Physician Training/Certification

· The raw data from all sleep tests must be reviewed and the tests must be interpreted by either:

1. A Diplomate of the American Board of Sleep Medicine (ABSM) OR

2. A Diplomate in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS) OR

3. An active physician staff member of an AASM accredited sleep center or sleep laboratory OR

4. An active physician staff member of a Joint Commission accredited sleep laboratory OR

5. A Diplomate of the American Board of Family Medicine (ABFM) with Certificate of Added Qualifications (CAQ) in Sleep Medicine.

The globally billed professional/technical (PC/TC) components for services related to home sleep testing (G0398, G0399 or G0400) are covered for the purpose of testing a patient for the diagnosis of OSA if the home sleep testing is reasonable

and necessary for the diagnosis of the patient's condition, meets all other Medicare requirements, and the physician who performs the service meets the physician training/certification requirement.

FCSO Medicare will consider PSG, sleep studies, MSLT, and MWT reasonable and necessary when performed for the following medical conditions:

1. Narcolepsy – *This term refers to a syndrome that is characterized by abnormal sleep tendencies, e.g., excessive daytime sleepiness or disturbed nocturnal sleep. Related diagnostic testing is covered if the patient has inappropriate sleep episodes or attacks (e.g., while driving, in the middle of a meal, in the middle of a conversation), amnesiac episodes, or continuous disabling drowsiness. The sleep disorder clinic must submit documentation that this condition is severe enough to interfere with the patient's well being and health before Medicare benefits may be provided for diagnostic testing.* Ordinarily, a diagnosis of narcolepsy can be confirmed by demonstrating mean sleep latency of 10 minutes or less and two or more REM onset sleep periods during the MSLT.

The diagnosis of narcolepsy is usually confirmed by PSG followed by a MSLT. The following measurements are normally required to diagnose narcolepsy:

· PSG assessment of the quality and quantity of nighttime sleep;

· MSLT derived mean sleep latency;

· The number of REM onset sleep episodes on the MSLT.

Initial PSG and MSLT occasionally fail to identify narcolepsy. Repeat PSG may be indicated if:

· The first study is technically inadequate due to equipment failure;

· The subject could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;

· Initiation of therapy or confirmation of the efficacy of prescribed therapy is needed; or

· The results were inconclusive or ambiguous.

A clinical history, sleep diaries, PSG, and MSLT are key items in the evaluation of narcolepsy. PSG followed by MSLT is helpful in confirming the clinical impression but these tests assume greater significance if cataplexy is lacking. Cataplexy refers to the total or partial loss of muscle tone in response to sudden emotion. Narcoleptic patients often report disrupted sleep, and PSG often confirms fragmented sleep patterns.

FCSO Medicare does not cover HST in the evaluation of narcolepsy.

2. Sleep Apnea – *This is a potentially lethal condition where the patient stops breathing during sleep. Three types of sleep apnea have been described (central, obstructive, and mixed). The nature of the apnea episodes can be documented by* clinical sleep evaluation and *appropriate diagnostic testing.*

Abnormal breathing events in sleep apnea syndromes include apnea, hypopnea and respiratory effort related arousals (RERA). Apnea is a cessation of airflow for at least 10 seconds. Hypopnea is an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxyhemoglobin saturation. RERA is defined as a period during sleep lasting at least 10 seconds during which severe narrowing of the upper airways with increasing respiratory efforts leads to electroencephalographic arousal from sleep without an appreciable reduction in airflow and oxygen saturation.

Apneas can be classified as central, obstructive or mixed based on the presence of respiratory effort during the event. In obstructive apnea events, respiratory effort continues in the absence of airflow while in central apnea events, both airflow and respiratory effort are simultaneously absent. Mixed apnea events contain respiratory effort only during a portion of the apnea event.

OSA occurs when the muscles relax during sleep, causing soft tissue in the back of the throat to collapse and block the

upper airway. This leads to partial reductions (hypopneas) and complete pauses (apneas) in breathing during sleep. Most pauses last between 10 and 30 seconds, but some may persist for one minute or longer. This can lead to abrupt reductions in blood oxygen saturation. OSA characterized by RERA events has been called upper airway resistance syndrome. In central sleep apnea, the airway is not blocked but respiratory coordination is impaired such that the brain does not signal the muscles of respiration to contract. All sleep apnea syndromes disrupt sleep, leading to excessive daytime sleepiness, fatigue and cognitive disturbances. OSA has also been associated with elevated risk for arterial hypertension, cardiac ischemic events, cerebral vascular accidents, insulin resistance and obesity.

The diagnosis and severity of sleep apnea syndromes is established by the clinical evaluation and a positive PSG or HST. Staging of the severity of sleep apnea can be accomplished by utilization of the apnea-hypopnea index (AHI) which is defined as the average number of apneas and hypopneas per hour of sleep. The respiratory disturbance index (RDI) is another term used to establish the diagnosis of sleep apnea and stage its severity, which in sleep tests that measure sleep with EEG is defined as the average number of apneas and hypopneas, and RERA per hour of sleep. In Type III, Type IV HST, and in HST devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone where sleep is not measured, the RDI is defined as the average number of apneas and hypopneas per hour of recording.

Positive airway pressure (PAP) therapy is a non-invasive technique for providing continuous (CPAP) or variable levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in OSA. CPAP is the most commonly used treatment for OSA. The appropriate level for CPAP is best determined during a CPAP titration PSG. A titration PSG provides useful information on the appropriate level of CPAP during one single night in a dedicated environment. Other factors, such as body and neck or mandibular position, weight changes, and nasal obstruction may affect the appropriate CPAP level. Since these effects may change over time, automatically-adjusting positive airway pressure devices (APAP) were developed. APAP devices are designed to automatically match the treatment pressure to the patient's needs. APAP devices react to perceived treatment pressure needs by manufacturer specific processes such that the information derived from APAP may differ by device and manufacturer. Certain APAP devices may be used in an unattended way to determine a fixed CPAP treatment pressure for patients with moderate to severe OSA without significant co-morbidities such as congestive heart failure, chronic obstructive pulmonary disease, central sleep apnea syndromes and hypoventilation syndromes. Similarly, certain APAP devices may be initiated and used in the self-adjusting mode for unattended treatment of patients previously diagnosed with moderate to severe OSA without the significant co-morbidities earlier described. A clear patient preference for APAP over manual CPAP has not been demonstrated by studies addressing the issue.

Bilevel positive airway pressure (BPAP) is a positive pressure treatment alternative to CPAP that delivers different pressures during exhalation and inhalation. The inhalation pressure does not adapt to the patient's changing needs, as in the APAP, but the exhalation pressure can be adjusted lower. The ability to set different inhalation and exhalation pressures results in lower average airway pressures than those delivered by CPAP. Using lower pressures may reduce the incidence of side effects, such as the sensation of suffocation, difficulty exhaling, nasal congestion, etc. which contribute to patient noncompliance. A clear patient preference for BPAP over CPAP has not been demonstrated by studies addressing the issue.

PSG and HST are routinely indicated when used to establish the diagnosis of sleep apnea. PSG, but not HST, is routinely indicated for PAP titration in patients with sleep apnea previously diagnosed by a clinical evaluation and either a positive PSG or a Medicare covered HST. PSG is also routinely indicated to evaluate for the presence of OSA in patients before they undergo surgical intervention for snoring. Follow-up PSG is routinely indicated for the assessment of treatment results in the following circumstances:

1. After good clinical response to oral appliance treatment in patients with OSA, to ensure therapeutic benefit;

2. After surgical treatment of patients with OSA, to ensure satisfactory response; or

3. After surgical treatment of patients with OSA whose symptoms return despite a good initial response to treatment.

4. After substantial weight loss has occurred in patients on PAP for treatment of OSA to ascertain whether PAP is still needed at the previously titrated pressure;

5. After substantial weight gain has occurred in patients previously treated with PAP successfully, who are again symptomatic despite the continued use of PAP, to ascertain whether pressure adjustments are needed; or

6. When clinical response is insufficient or when symptoms return despite a good initial response to treatment with PAP.

Follow-up PSG is not routinely indicated in patients treated with PAP whose symptoms continue to be resolved with PAP treatment.

A MSLT is not routinely indicated for most patients with sleep apnea.

Ordinarily, a single PSG or HST can diagnose adult OSA. However, if the beneficiary's treating physician has good reason to believe that the result of an HST is insufficient in light of the beneficiary's clinical findings, a subsequent diagnostic PSG could be performed. Such retest decisions would be made on a case-by-case basis. The routine use of a two test routine (HST followed by PSG) to diagnose sleep apnea would not be considered reasonable and necessary. If more than one PSG or HST diagnostic testing session is claimed, persuasive medical evidence justifying the medical necessity for the additional tests will be required.

Ordinarily a single PSG is sufficient to titrate PAP therapy. However, repeat PAP titration PSG may be indicated when the clinical response is insufficient or when initial CPAP was not tolerated and BPAP is to be used in lieu of CPAP. The routine use of more than one PSG to titrate PAP therapy would not be considered reasonable and necessary. If more than one PAP titration PSG is claimed, persuasive medical evidence justifying the medical necessity for the additional tests will be required.

Effective for claims with dates of service on and after March 13, 2008, Medicare will allow for coverage of CPAP therapy when used in adult patients based upon a diagnosis of OSA by PSG or HST as contained in section 240.4 of Pub 100-03 of the Medicare NCD Manual. (See the DME MAC local coverage determination for "Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea" for coverage of CPAP devices.)

For a diagnosis of OSA to be made, the following criteria must be met:

A. Prior to sleep testing, the patient has a face-to-face clinical evaluation by the treating physician to assess the patient for OSA which must include, at a minimum, the following:

1. Sleep history and symptoms including, but not limited to, snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches; and,

2. Epworth Sleepiness Scale; and,

3. Physical examination that documents body mass index, neck circumference and a focused cardiopulmonary and upper airway system evaluation.

B. The patient has a Medicare-covered sleep test that meets either of the following criteria:

1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,

2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:

a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,

b. Hypertension, ischemic heart disease, or history of stroke

CPAP based on clinical diagnosis alone or using a diagnostic procedure other than PSG or Type II, Type III, Type IV HST measuring at least three channels, or an HST device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered only when provided in the context of a clinic study pursuant to CMS Coverage with Evidence Development as described in CMS Publication 100-03, Medicare NCD Manual, Section 240.4.

3. Other Respiratory Disorders - This diagnostic category includes breathing disorders that are not principally defined by obstructive or central apnea/hypopnea or the upper airways resistance syndrome.

PSG is indicated for patients with neuromuscular disorder and sleep-related symptoms to evaluate symptoms of sleep disorder that are not adequately diagnosed by obtaining a sleep history, assessing sleep hygiene, and reviewing sleep diaries.

PSG and HST are not indicated to diagnose chronic lung disease. Nocturnal hypoxemia in patients with chronic obstructive, restrictive, or reactive lung disease is usually adequately evaluated by oximetry and does not require PSG or HST. However, if the patient's symptoms suggest a diagnosis of obstructive sleep apnea or periodic limb movement disorder, indications for PSG are the same as for those disorders in patients without chronic lung disease.

FCSO Medicare does not cover HST for these conditions.

4. Impotence – *Diagnostic nocturnal penile tumescence testing may be covered, under limited circumstances, to determine whether erectile impotence in men is organic or psychogenic. Although impotence is not a sleep disorder, the nature of the testing requires that it be performed during sleep. The tests ordinarily are covered only where necessary to confirm the treatment to be given (surgical, medical, or psychotherapeutic). Ordinarily, a diagnosis may be determined by two nights of diagnostic testing. If more than two nights of testing are claimed, persuasive medical evidence justifying the medical necessity for the additional tests will be required.*

FCSO Medicare does not cover HST in the evaluation of impotence.

5. Parasomnia - *Parasomnias are a group of conditions that represent undesirable or unpleasant occurrences during sleep. Behavior during these times can often lead to damage to the surroundings and injury to the patient or to others. Parasomnia may include conditions such as sleepwalking, sleep terrors, and rapid eye movement (REM) sleep behavior disorders. In many of these cases, the nature of these conditions may be established by careful clinical evaluation. Suspected seizure disorders as possible cause of the parasomnia are appropriately evaluated by standard or prolonged sleep EEG studies. In cases where seizure disorders have been ruled out and in cases that present a history of repeated violent or injurious episodes during sleep, polysomnography may be useful in providing a diagnostic classification or prognosis.* In parasomnia, PSG is routinely indicated:

· To assist with the diagnosis of paroxysmal arousals or other sleep disruptions that are thought to be seizure related when the initial clinical evaluation and results of a standard EEG are inconclusive.

· In evaluating sleep-related behaviors that are violent or otherwise potentially injurious to the patient or others.

· 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 (e.g. stereotypical, repetitive, or focal).

In parasomnia, PSG may be indicated under the following circumstances:

· In situations with forensic considerations (e.g. if onset follows trauma or if the events themselves have been associated with personal injury).

· When the presumed parasomnia or sleep-related epilepsy does not respond to conventional therapy.

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

PSG is not routinely indicated for patients with epilepsy who have no specific complaints consistent with a sleep disorder.

FCSO Medicare does not cover HST in the evaluation of parasomnia.

6. Restless Legs Syndrome and Periodic Limb Movement Disorder - Restless legs syndrome is a neurologic disorder characterized by disagreeable leg sensations that usually occur at rest or before sleep and are alleviated by motor

activity. Periodic limb movements are involuntary, stereotypic, repetitive limb movements that may occur during sleep and usually involve the legs and, occasionally, the arms. Periodic limb movements during sleep often accompany restless legs syndrome. Periodic limb movement disorder is a sleep disorder characterized by periodic limb movements that cause frequent arousals and lead to insomnia or excessive daytime sleepiness. The results of PSG studies from patients with severe restless legs syndrome often show prolonged sleep latencies, decreased sleep efficiency, increased number of awakenings, significant reductions in total sleep time, and decreased amounts of slow-wave sleep. Patients with periodic limb movement disorder often have frequent periodic limb movements that are associated with arousals and awakenings, reduced total sleep time, and decreased sleep efficiency.

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 movements during sleep and frequent awakenings, fragmented sleep, difficulty maintaining sleep, or excessive daytime sleepiness.

PSG is not routinely indicated to diagnose or treat restless legs syndrome.

FCSO Medicare does not cover HST in the evaluation of either restless legs syndrome or periodic limb movements of sleep.

Other Limitations of Coverage:

Diagnostic testing that is duplicative of previous sleep testing done by the attending physician to the extent the results are still pertinent is not covered because it is not reasonable and necessary.

Polysomnography (PSG and HST) *for chronic insomnia is not covered.*

· *Evidence at the present time is not convincing that polysomnography* (PSG) *in a sleep disorder clinic* (center or laboratory or HST) *for chronic insomnia provides definitive diagnostic data or that such information is useful in patient treatment or is associated with improved clinical outcome. The use of polysomnography* (PSG or HST) *for diagnosis of patients with chronic insomnia is not covered under Medicare because it is not reasonable and necessary under § 1862(a)(1)(A) of the Act.*

Circadian rhythm sleep disorders:

· Circadian rhythm sleep disorders result from a mismatch between an individual's sleep pattern and the timing and amount of sleep that the person desires, needs, requires, or expects. The six types of rhythm disorders are time zone change (jet lag) disorder, shift work disorder, irregular sleep-wake patterns, delayed sleep-phase syndrome, advanced sleep-phase syndrome, and non-24-hour sleep-wake disorder.

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

FCSO Medicare does not cover HST for chronic insomnia and circadian rhythm sleep disorders.

Coding Information

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Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x	Not Applicable

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced

by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999	Not Applicable

CPT/HCPCS Codes

G0400 Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels (Devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone are covered under this code.)	
95805	MULTIPLE SLEEP LATENCY OR MAINTENANCE OF WAKEFULNESS TESTING, RECORDING, ANALYSIS AND INTERPRETATION OF PHYSIOLOGICAL MEASUREMENTS OF SLEEP DURING MULTIPLE TRIALS TO ASSESS SLEEPINESS
95807	SLEEP STUDY, SIMULTANEOUS RECORDING OF VENTILATION, RESPIRATORY EFFORT, ECG OR HEART RATE, AND OXYGEN SATURATION, ATTENDED BY A TECHNOLOGIST
95808	POLYSOMNOGRAPHY; SLEEP STAGING WITH 1-3 ADDITIONAL PARAMETERS OF SLEEP, ATTENDED BY A TECHNOLOGIST
95810	POLYSOMNOGRAPHY; SLEEP STAGING WITH 4 OR MORE ADDITIONAL PARAMETERS OF SLEEP, ATTENDED BY A TECHNOLOGIST
95811	POLYSOMNOGRAPHY; 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
G0398	HOME SLEEP STUDY TEST (HST) WITH TYPE II PORTABLE MONITOR, UNATTENDED; MINIMUM OF 7 CHANNELS: EEG, EOG, EMG, ECG/HEART RATE, AIRFLOW, RESPIRATORY EFFORT AND OXYGEN SATURATION
G0399	HOME SLEEP TEST (HST) WITH TYPE III PORTABLE MONITOR, UNATTENDED; MINIMUM OF 4 CHANNELS: 2 RESPIRATORY MOVEMENT/AIRFLOW, 1 ECG/HEART RATE AND 1 OXYGEN SATURATION
G0400	HOME SLEEP TEST (HST) WITH TYPE IV PORTABLE MONITOR, UNATTENDED; MINIMUM OF 3 CHANNELS

ICD-9 Codes that Support Medical Necessity

302.72*	PSYCHOSEXUAL DYSFUNCTION WITH INHIBITED SEXUAL EXCITEMENT
307.46*	SLEEP AROUSAL DISORDER
307.47*	OTHER DYSFUNCTIONS OF SLEEP STAGES OR AROUSAL FROM SLEEP
307.48*	REPETITIVE INTRUSIONS OF SLEEP
327.10	ORGANIC HYPERSOMNIA, UNSPECIFIED
327.11	IDIOPATHIC HYPERSOMNIA WITH LONG SLEEP TIME
327.12	IDIOPATHIC HYPERSOMNIA WITHOUT LONG SLEEP TIME
327.20	ORGANIC SLEEP APNEA, UNSPECIFIED
327.21	PRIMARY CENTRAL SLEEP APNEA
327.23	OBSTRUCTIVE SLEEP APNEA (ADULT) (PEDIATRIC)
327.24	IDIOPATHIC SLEEP RELATED NON OBSTRUCTIVE ALVEOLAR HYPOVENTILATION
327.25	CONGENITAL CENTRAL ALVEOLAR HYPOVENTILATION SYNDROME
327.26	SLEEP RELATED HYPOVENTILATION/HYPOXEMIA IN CONDITIONS CLASSIFIABLE ELSEWHERE
327.27	CENTRAL SLEEP APNEA IN CONDITIONS CLASSIFIED ELSEWHERE
327.29	OTHER ORGANIC SLEEP APNEA
327.40	ORGANIC PARASOMNIA, UNSPECIFIED
327.41	CONFUSIONAL AROUSALS
327.42	REM SLEEP BEHAVIOR DISORDER
327.43	RECURRENT ISOLATED SLEEP PARALYSIS
327.44	PARASOMNIA IN CONDITIONS CLASSIFIED ELSEWHERE
327.49*	OTHER ORGANIC PARASOMNIA
327.51*	PERIODIC LIMB MOVEMENT DISORDER
345.80	OTHER FORMS OF EPILEPSY AND RECURRENT SEIZURES, WITHOUT MENTION OF INTRACTABLE EPILEPSY
345.81*	OTHER FORMS OF EPILEPSY AND RECURRENT SEIZURES, WITH INTRACTABLE EPILEPSY
347.00	NARCOLEPSY, WITHOUT CATAPLEXY

347.01	NARCOLEPSY, WITH CATAPLEXY
347.10	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE, WITHOUT CATAPLEXY
347.11*	NARCOLEPSY IN CONDITIONS CLASSIFIED ELSEWHERE, WITH CATAPLEXY
607.84*	IMPOTENCE OF ORGANIC ORIGIN
780.51	INSOMNIA WITH SLEEP APNEA, UNSPECIFIED
780.53	HYPERSOMNIA WITH SLEEP APNEA, UNSPECIFIED
780.54	HYPERSOMNIA, UNSPECIFIED
780.56*	DYSFUNCTIONS ASSOCIATED WITH SLEEP STAGES OR AROUSAL FROM SLEEP
780.57	UNSPECIFIED SLEEP APNEA
799.02	HYPOXEMIA

* These additional ICD-9-CM codes are to be used with CPT codes 95805, 95807, 95808, 95810 or 95811 only, as appropriate.

Diagnoses that Support Medical Necessity

See ICD-9 Codes that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

XX000	Not Applicable

Diagnoses that DO NOT Support Medical Necessity

All other diagnoses not listed as covered in the “ICD-9 Codes that Support Medical Necessity” section of this LCD.

General Information

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Documentation Requirements

Documentation / Credentialing Requirements

Accreditation

· All centers billing sleep studies must maintain proper certification / accreditation documentation on file that indicates it is accredited by the AASM or that it is accredited as a sleep laboratory by the Joint Commission. This documentation must be available to Medicare upon request.

· The TC of PSG and Sleep Testing (including HST) facilities (hospital based or affiliated) and free standing facilities (office/clinic, IDTFs, and any non-hospital based facilities where sleep studies are performed) that are not currently accredited will have until April 30, 2010 to obtain the required accreditation.

Physician Training/Certification

· All sleep tests must be reviewed and the tests must be interpreted by either:

1. A Diplomate of the American Board of Sleep Medicine (ABSM) OR

2. A Diplomate in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS) OR

3. An active physician staff member of an AASM accredited sleep center or sleep laboratory OR

4. An active physician staff member of a Joint Commission accredited sleep laboratory OR

5. A Diplomate of the American Board of Family Medicine (ABFM) with Certificate of Added Qualifications (CAQ) in Sleep Medicine.

Technician Credentials/Training

· Sleep technicians or technologists attending PSG or sleep studies affiliated with HST must have appropriate personnel

certification. Examples of certification in PSG and sleep technology for non-physician personnel include:

1. Registered Polysomnography Technologist (RPSGT)

2. Registered Electroencephalographic technologist (R. EEG T.) – Polysomnography

Credentialing must be provided by nationally recognized credentialing organizations such as:

1. Board of Registered Polysomnographic Technologists (BRPT) that
provides (RPSGT) credential; OR

2. American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET) that provides R. EEG T.) – Polysomnography credential; OR

3. Performed in a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), or Joint Commission on Accreditation of Healthcare Organizations (JCAHO); OR

4. American Board of Sleep Medicine (ABSM) that provides credentialing in sleep technology; OR

5. National Board for Respiratory Care, Inc. (NBRC) that provides specialty examination for respiratory therapists performing sleep disorders testing and therapeutic intervention (CRT-SDS and RRT-SDS)

· Prior to ordering the tests, the patient must have a face-to-face clinical evaluation by a physician. The evaluation must include:

1. A sleep history and physical examination including, but not limited to, snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches; and,

2. Epworth sleepiness scale; and,

3. Physical examination that documents body mass index, neck circumference and a focused cardiopulmonary and upper airway evaluation.

· When billing for a sleep disorder test, the ordering physician's NPI must be indicated on the claim form and the order kept on record.

· The center/laboratory must maintain and provide to Medicare upon request sufficient documentation that the narcolepsy patient is severe enough to interfere with the patient's well being and health before Medicare benefits are provided for diagnostic testing.

· If more than two nights of testing are performed, documentation justifying the medical necessity for the additional test(s) must be provided to Medicare upon request.

Home Sleep Testing

The technical component of HST (G0398, G0399 and G0400) must be provided by an accredited sleep center or laboratory as noted above and meet the requirements of the LCD for coverage. The only exception would be the global billing (professional/technical components [PC/TC]) by an office based physician who is a diplomate of the ABSM or diplomate in sleep medicine by a member board of the ABMS or is an active staff member of an accredited sleep center that is separate from or part of the office/clinic. In this case, the PC/TC for HST can be covered for the purpose of testing a patient for the diagnosis of OSA if the home sleep testing is reasonable and necessary for the diagnosis of the patient's condition as outlined in the LCD, and the office based technician doing the patient instruction and HST scoring meet the training/credentialing requirements as outlined above. Under this circumstance, the physician would be the interpreter of the test and bill globally.

In general, pursuant to 42 CFR 410.32(a) diagnostic tests that are not ordered by the beneficiary's treating physician are not considered reasonable and necessary. Pursuant to 42 CFR 410.32(b) diagnostic tests payable under the physician fee

schedule that are furnished without the required level of supervision by a physician are not reasonable and necessary.

Appendices

Utilization Guidelines

More than one HST per year interval would not be expected. If more than one HST session is performed for suspected OSA, persuasive medical evidence justifying the medical necessity for the additional tests will be required. Similarly, more than two PSG per year interval would not be expected. If more than two PSG sessions are performed for the diagnosis or adjustment of treatment of sleep, pervasive medical evidence justifying the medical necessity for the additional tests will be required upon request. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

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Other Medicare Contractors' LCDs.

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Advisory Committee Meeting Notes

This Local Coverage Determination (LCD) does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Florida Contractor Advisory Committee Meeting held on March 7, 2009.

Puerto Rico/U.S. Virgin Islands Contractor Advisory Meeting held on March 19, 2009.

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

06/01/2010

Revision History Number

2

Revision History Explanation

Revision Number:2
Start Date of Comment Period:N/A
Start Date of Notice Period:06/01/2010
Revised Effective Date:05/18/2010

LCR B2010-048
May 2010 Update

Explanation of Revision: Revisions to the Indications and Limitations and Documentation Requirements sections of the LCD to add an additional Physician Training/Certification qualification as acceptable for the services outlined in the LCD. The effective date of this revision is based on date of service.

Revision Number:1
Start Date of Comment Period:N/A
Start Date of Notice Period:08/01/2009

Revised Effective Date: 07/21/2009

LCR B2009-081
July 2009 Update

Explanation of Revision: Under the “Indications and Limitation of Coverage and/or Medical Necessity” section, added CMS verbiage to the Type I devices. This is effective for claims processed on or after 08/10/2009 for dates of service on or after 03/03/2009 based on CR 6534. Under the “Indications of Coverage” portion of this section, added verbiage for clarification of Accreditation and Physician Training/Certification requirements. Under the “Documentation/Credentialing Requirements” section, added verbiage for clarification of accreditation requirements, sub headings of “Physician Training/Certification,” “Technician Credentials/Training” and information regarding “Home Sleep Testing.” In addition, the “Sources of Information and Basis for Decision” section was updated. The date of these revisions is effective for dates of service on or after 07/21/2009.

Revision Number:Original
Start Date of Comment Period:02/20/2009
Start Date of Notice Period:05/01/2009
Original Effective Date: 06/30/2009

LCR B2009-064
April 2009 Update

11/21/2010 - For the following CPT/HCPCS codes either the short description and/or the long description was changed. Depending on which description is used in this LCD, there may not be any change in how the code displays in the document:
95807 descriptor was changed in Group 1
95808 descriptor was changed in Group 1
95810 descriptor was changed in Group 1

Reason For Change

Last Reviewed On Date

Related Documents

This LCD has no Related Documents.

LCD Attachments

Attachments such as Coding Guidelines and Comment Summaries are available in the Medicare coverage database located on the Centers for Medicare & Medicaid Services (CMS) website. To view attachments, go to http://www.cms.gov/MCD/search.asp?clickon=search and enter the LCD ID in the search window; when the LCD is displayed select LCD Attachments from the "Jump to Section" dropdown list.

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