LCD L32711 - OUTPATIENT SLEEP STUDIES

Contractor Information

Contractor Name: Novitas Solutions, Inc.
Contractor Number(s): 04911, 07101, 07102, 07201, 07202, 07301, 07302, 04111, 04112, 04211, 04212, 04311, 04312, 04411, 04412
Contractor Type: MAC Part A & B

LCD Information

Document Information

LCD ID Number
L32711

LCD Title
OUTPATIENT SLEEP STUDIES

Contractor's Determination Number
L32711

Primary Geographic Jurisdiction
Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, New Mexico

Oversight Region
Central Office

Original Determination Effective Date
For services performed on or after 08/13/2012

Original Determination Ending Date
N/A

Revision Effective Date
For services performed on or after 01/01/2013

Revision Ending Date
N/A

CMS National Coverage Policy

Language quoted from Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (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:

Title XVIII of the Social Security Act (SSA):

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.
Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

**Code of Federal Regulations:**

42 CFR Section 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements).

**Federal Register:**

Federal Register, Vol. 65, No. 68, April 7, 2000, page. 18434 is the Medicare Program Prospective Payment System for Hospital Outpatient Services Final Rule.

**CMS Publications:**

CMS Publication 100-2, Medicare Benefit Policy Manual, Chapter 6:50 Sleep Disorder Clinics

CMS Publication 100-2, Medicare Benefit Policy Manual, Chapter 15:70 Sleep Disorder Clinics

CMS Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1: 30.4 Electrosleep Therapy

CMS Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1: 240.4 Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (Effective April 4, 2005) and Final Decision Memo on CPAP therapy dated March 13, 2008.

CMS Publication 100-4, Medicare Claims Processing Manual, Chapter 4, provides information on the Outpatient Prospective Payment System (OPPS).

Change Request 6534, Transmittal 103, July 10, 2009 Sleep Testing for Obstructive Sleep Apnea.

**Jurisdiction “H” Notice:**

Jurisdiction “H” comprises the states of Arkansas, Louisiana, Mississippi, Colorado, New Mexico, Oklahoma, and Texas. Novitas is responsible for claims payment and Local Coverage Determination (LCD) development for this jurisdiction. This LCD was created as a part of the legacy transition (8/13/2012 – 11/19/2012); and, is a consolidation of the previous legacy contractors’ policies. Coverage of each LCD begins when the state/contract number combination officially is integrated into the Jurisdiction. On the CMS MCD, this date is known as either the Original Effective Date or the Revision Effective Date. The following table details the official effective dates for each state/contract number combination.

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Indications and Limitations of Coverage and/or Medical Necessity

Abstract

Sleep complaints and disorders are widespread. Although approximately 40 million Americans suffer from chronic sleep disorders, 95% of these are undiagnosed and untreated. The aging process places elderly persons at risk for sleep disturbances as the amount of time spent in deeper levels of sleep diminishes. Many sleep disorders can be managed by primary care physicians; however, when abnormal sleep patterns are not easily explainable and further evaluation is necessary, sleep studies may be needed.

Normal nocturnal sleep in adults displays a consistent organization from night to night. Sleep consists of two distinct states: rapid eye movement (REM), also called dream sleep and non-rapid eye movement (NREM), which is divided into four stages. NREM stages 1 and 2 are referred to as light sleep and stages 3 and 4 as deep or slow-wave sleep. Dreaming occurs mostly in REM. Sleep is a cyclic phenomenon, with four or five REM periods during the night accounting for about one-fourth of the total night's sleep (1 1/2 - 2 hours).

Sleep studies and polysomnography refer to the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep for 6 or more hours with physician review, interpretation and report. 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). Polysomnography is distinguished from sleep studies by the inclusion of sleep staging.

Polysomnography is defined to include, but is not limited to, the following:

- A 1-4 lead electroencephalogram (EEG) to measure global neural encephalographic activity using electrodes placed on the scalp
- Electrooculogram (EOG) to measure eye movements using electrodes placed near the outer canthus of each eye
- A submental electromyogram (EMG) to measure submental electromyographic activity using electrodes placed over the mentalis, submentalis muscle, and/or masseter regions
- Rhythm electrocardiogram (ECG) with two or three chest leads
- Nasal and/or oral airflow via mercury switches or by direct observation
- Ventilation and respiratory effort by chest-wall and abdominal movement measured using strain gauges, piezoelectric belts, inductive plethysmography, impedance or inductance pneumography, endoesophageal pressure, or by intercostal EMG
- Gas exchange (oxygen saturation (SpO2)) by oximetry, transcutaneous monitoring, or end-tidal gas analysis
- Extremity muscle activity, motor activity-movement using EMG
- Body positions via mercury switches or by direct observation
- Recordings of vibration (frequency and/or volume) may be recorded
- Transcutaneous CO2, esophageal pH, penile tumescence, and bipolar EEG

Multiple sleep latency testing (MSLT) involves several 20-minute nap opportunities (usually 4-5) 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.

Sleep disorder clinics are facilities in which certain conditions are diagnosed through the study of sleep. Such clinics are for diagnosis, therapy, and research. Sleep disorder clinics may provide some diagnostic or therapeutic services that are covered under Medicare. These clinics may be affiliated either with a hospital or a freestanding facility. Whether a clinic 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. (CMS Publication 100-2, Medicare Benefit Policy Manual, Chapter 6, Section 50).

All Sleep studies to be considered reasonable and necessary shall be performed in or under the direct supervision of a hospital sleep laboratory, a sleep clinic that is a direct extension of a physician’s office or by an Independent Diagnostic Treatment Facility (IDTF). Each facility shall be supervised or under the directorship of a physician (MD/DO) trained in analyzing and interpreting the recordings who is Board Certified by the American Academy of Sleep Medicine (AASM), American Board of Medical Specialties in
Sleep Medicine (ABMS) or board eligible for these credentials AND should be attended by an appropriately trained technologist. (Please see the Documentation Requirements for acceptable list of technical support for these studies.)

In addition the non-hospital based sleep clinic or IDTF shall be certified by the American Academy of Sleep Medicine, The Joint Commission (formerly known as JCAHO), or Accreditation Commission for Health Care, Inc. (ACHC).

Sleep studies performed in the home shall only be covered under special circumstances listed below under ‘Home Sleep Testing (HST) or Portable Monitoring (PM)’. All home sleep studies, to be covered must be under the supervision of the hospital based sleep lab, a sleep clinic that is a direct extension of the physician’s office or an IDTF.

Indications

A - Criteria for Coverage of Diagnostic Tests and therapeutic tests.

All reasonable and necessary diagnostic tests given for the medical conditions listed in subsection B are covered when the following criteria are met:

- The hospital-based clinic is under the direction and control of physicians that are board certified or eligible in sleep medicine. All non hospital based facilities in addition must be certified by the AASM, The Joint Commission, or ACHC. Diagnostic testing routinely performed in sleep disorder clinics 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 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.

Diagnostic testing that is duplicative of previous testing done by the attending physician to the extent the results are still pertinent is not covered because it is not reasonable and necessary under §1862(a)(1)(A) of the Act. (CMS Publication 100-2, Medicare Benefit Policy Manual, Chapter 15, Section 70).

B - Medical Conditions for Which Testing is Covered

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. The overnight TESTING is considered an integral part of these tests.

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 confirmed by a MSLT Study. If more than one MSLT study is claimed, persuasive medical evidence justifying the medical necessity for the additional test(s) [will be required].

The diagnosis of narcolepsy is usually confirmed by an overnight sleep study (polysomnography) that is facility based followed by a multiple sleep latency test (MSLT) that is likewise facility based. The following measurements are normally required to diagnose narcolepsy:

- Polysomnographic assessment of the quality and quantity of nighttime sleep;
- Determination of the latency of the first REM episode;
- MSLT; and
- The presence of REM-sleep episodes.

Initial polysomnography and MSLT occasionally fail to identify narcolepsy.

Repeat polysomnography may be indicated and is usually facility based:

- if the first study is technically inadequate due to equipment failure;
- if the subject could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;
- if initiation of therapy or confirmation of the efficacy of prescribed therapy is needed; or
• if the results were inconclusive or ambiguous.

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 appropriate diagnostic testing. Ordinarily, a single polysomnogram and electroencephalogram (EEG) can diagnose sleep apnea. If more than one such testing session is claimed, persuasive medical evidence justifying the medical necessity for the additional tests will be required. (CMS Publication 100-2, Medicare Benefit Policy Manual, Chapter 15, Section 70). Testing by type III or IV devices can also be covered under special circumstances. See definitions below as were as HST section below.

Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent oxygen desaturation (CMS Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 240.4 [Rev.35, 05-06-05]).

Sleep apnea may be due to an occlusion of the airway (obstructive apnea), absence of respiratory effort (central sleep apnea) or a combination of these factors (mixed sleep apnea).

Obstructive sleep apnea (OSA) may be caused by one of the following:

• Reduced upper airway caliber due to obesity;
• Adenotonsillar hypertrophy;
• Mandibular deficiency;
• Macroglossia;
• Upper airway tumor;
• Excessive pressure across the collapsible segment of the upper airway;
• Activity of the muscles of the upper airway insufficient to maintain patency.

Diagnosis of obstructive sleep apnea requires documentation of:

• AHI [Apnea-Hypopnea Index] /RDI greater than or equal to 15 events per hour, or
• AHI greater than or equal to 5 and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

*The [Apnea-Hypopnea Index] AHI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 30 episodes recorded by polysomnography using actual recorded hours of sleep without symptoms and 10 episodes with symptoms above. (CMS Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 240.4 [Rev.35, 05-06-0]).

**The Respiratory Disturbance Index (RDI) is defined as the number of apneas and hypopneas per hour of recording time.

CPAP [Continuous Positive Airway Pressure] is a non-invasive technique for providing single 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 obstructive sleep apnea (OSA). (CMS Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 240.4).

The use of CPAP devices is covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adult patients with OSA if either of the AHI/RDI criteria mentioned above are met.

The polysomnography, Type II, III or Type IV devices as defined below must be performed in a facility-based sleep study laboratory or by portable monitoring (including in other parts of a facility, out of facility, or at home testing) under the restrictions listed below and with the credentialing requirements being met. Initial claims must be supported by medical documentation (separate documentation where electronic billing is used) with documentation of medical necessity.

The claim must also certify that the documentation supporting a diagnosis of OSA (described above) is available. (CMS Publication 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 240.4. [Rev.35, 05-06-05]).

For patients with severe and unambiguous obstructive sleep apnea, the initiation of treatment with nasal
CPAP may be incorporated into the diagnostic study night. This is called a "split-night" study (initial diagnostic polysomnogram followed by CPAP titration during polysomnography on the same night). A split night study is an overnight polysomnogram in which the patient spends the first half of the night being monitored for sleep apnea. In the event the study shows severe enough disease to merit treatment with CPAP (refer to the Medicare DME LCD on CPAP requirements), the technologist will place the patient on CPAP and will adjust the pressure on the CPAP to treat the underlying sleep apnea. This approach may be an alternative to one full night of diagnostic polysomnography followed by a second night of titration as long as:

- CPAP titration is carried out for more than 3 hours; and
- Polysomnography documents that CPAP eliminates or nearly eliminates the respiratory events during REM and NREM sleep.

Repeat polysomnography or sleep testing for diagnosing sleep apnea requires documentation justifying the medical necessity for the repeated test. Repeat polysomnography/sleep testing may be indicated:

- if the first study is technically inadequate due to equipment failure;
- if the subject could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;
- if the results were inconclusive or ambiguous; or
- if initiation of therapy or confirmation of the efficacy of prescribed therapy is needed.

Follow-up polysomnography or sleep studies are not routinely indicated for patients treated with CPAP whose symptoms continue to be resolved with CPAP treatment. Follow-up polysomnography studies may be indicated, however, for the following conditions:

- After substantial weight loss has occurred in patients on CPAP for treatment of sleep-related breathing disorders to ascertain whether CPAP is still needed at the previously titrated pressure;
- After substantial weight gain has occurred in patients previously treated with CPAP successfully, who are again symptomatic despite the continued use of CPAP, to ascertain whether pressure adjustments are needed; or
- When clinical response is insufficient or when symptoms return despite a good initial response to treatment with CPAP.

3. 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. (CMS Publication 100-2, Medicare Benefit Policy Manual, Chapter 15, Section 70). These studies shall not be performed in the home.

Normally, a clinical history, neurologic examination, and routine EEG obtained while the patient is awake and asleep are often sufficient to establish the diagnosis and permit the appropriate treatment of sleep-related epilepsy. In addition, common, uncomplicated, non-injurious parasomnias, such as typical disorders of arousal, nightmares, enuresis, somniloquy, and bruxism can usually be diagnosed by clinical evaluation alone.

Polysomnography is indicated to provide a diagnostic classification or prognosis when both of the following exist:

- When the clinical evaluation and results of standard EEG have ruled out a seizure disorder; and
- In cases that present a history of episodes during sleep that result in harm to the patient or others.

When polysomnography is performed for the diagnosis of parasomnias, the following measurements are obtained:

- Sleep-scoring channels (EEG, EOG, chin EMG);
- EEG using an expanded bilateral montage;
- EMG for body movements;
- Audiovisual recording; and
- Documented technologist observations.

**C - Polysomnography for Chronic Insomnia Is Not Covered.**
Evidence at the present time is not convincing that polysomnography in a sleep disorder clinic 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 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. (CMS Publication 100-2, Medicare Benefit Policy Manual, Chapter 15, Section 70).

D. Coverage of Therapeutic Services.

Sleep disorder clinics may at times render therapeutic as well as diagnostic services. Therapeutic services may be covered in a hospital outpatient setting or in a freestanding facility provided they meet pertinent requirements for the particular type of services and are reasonable and necessary for the patient, and are performed under the direct personal supervision of a physician. (CMS Publication 100-2, Medicare Benefit Policy Manual, Chapter 15, Section 70).

Limitations

Diagnostic testing that is duplicative of previous sleep testing done by the attending physician to the extent that the previous results are still pertinent is not covered, because it is not reasonable and necessary if there have been no significant clinical changes in the patient's medical history since the previous study.

Polysomnography or sleep studies, and MSLT are not covered in the following situations:

- For the diagnosis of patients with chronic insomnia;
- To preoperatively evaluate a patient for laser-assisted uvulopalatopharyngoplasty without clinical evidence that obstructive sleep apnea is suspected;
- To diagnose chronic lung disease (nocturnal hypoxemia in patients with chronic, obstructive, restrictive or reactive lung disease is usually adequately evaluated by oximetry; however, if the patient's sign/symptoms suggest a diagnosis of obstructive sleep apnea, polysomnography may be considered medically necessary);
- In cases where seizure disorders have not been ruled out;
- In cases of typical, uncomplicated and non-injurious parasomnias when the diagnosis is clearly delineated;
- For patients with epilepsy who have no specific complaints consistent with a sleep disorder;
- For patients with symptoms suggestive of periodic limb movement disorder or restless leg syndrome unless symptoms are suspected of being related to a covered indication;
- For the diagnosis of insomnia related to depression;
- For the diagnosis of circadian rhythm sleep disorders (i.e., rapid time-zone change [jet lag], shift-work sleep disorder, delayed sleep phase syndrome, advanced sleep phase syndrome, and non-24 hour sleep/wake disorder).

Home Sleep Testing (HST), Portable Monitoring (PM) or Out of the Facility (OOF) Testing

When the diagnostic evaluation of sleep disorders requires overnight examination of the sleeping patient by means of polysomnography to assess severity, effect on sleep architecture and continuity, and the effects on gas exchange, cardiac function, etc. the polysomnography is used in conjunction with the patient's history, other laboratory tests and observations, and the physician's knowledge of sleep disorders to reach a diagnosis and to recommend appropriate treatment and follow-up.

A Final Decision Memo (FDM) was issued by CMS on March 13, 2009 concerning Home Sleep Testing (HST) acceptance for coverage to determining need for CPAP.

Several issues were unanswered by this FDM. This LCD shall attempt to clarify under what circumstances this type of testing (i.e., Portable Monitoring, Out of Facility testing, and Home Sleep Testing) will be considered reasonable and necessary and therefore payable. The accuracy of diagnostic sleep studies depends on the knowledge, skill, and experience of the technologist and interpreter and does not matter if Type I, II, III, or IV or where the test is performed. Consequently, the providers of interpretations must be capable of demonstrating documented training and experience and maintain documentation for post-payment audit. (See "Documentation Requirements" section of this policy for certification/accreditation requirements.) Because patients referred for sleep studies must be evaluated thoroughly, the participation of a physician in the program is required. After evaluation, diagnosis, and the development of a treatment plan, patients are usually returned to their referring physicians, some patients will elect at least some treatment and follow-up with the sleep disorders program staff, particularly for prescription refills, the follow-up of nasal CPAP, etc. It is expected that ongoing education of the patient is an integral
part of the treatment.

Space, equipment, and staffing must be consistent with the requirements noted in the Documentation Requirements Section below.

- All studies and application of HST/PM/OOF testing devices must have face to face education and application performed by an acceptable technician before the study is performed as noted in the Documentation Requirement sections.
- All sleep studies (in facility or out of facility) are to be supervised and with an over read by the providers meeting the accreditation requirements list below in the Documentation Requirements Section to be considered reasonable and necessary and thereby payable.

All facility based (non-hospital affiliated) ordered sleep studies (in facility or OOF) shall be performed under the direction of a Center/Laboratory that meets the following criteria:

1. Each center/laboratory must have as medical director a physician with a license valid in the state of the center;
2. Technicians must work under the direction and control of a licensed physician, even though this test may be covered in the absence of direct supervision. This information should be documented and available upon request;
3. Each center/laboratory, non-hospital based, must be accredited by and comply with the standards set in the Documentation Requirements below to be considered reasonable and necessary and thereby payable. (AASM, The Joint Commission, ACHC).

Each center/laboratory in a freestanding center that is a direct extension of a physician's office associated with physician must have on staff (1) a physician/PhD psychologist who has the credentials listed in the Documentation Requirement Section or (2) special training in sleep medicine with the specialty designation of either pulmonary medicine, neurology, psychiatry, or otolaryngology so credentialed as noted in the Documentation Requirements Section below to be considered reasonable and necessary and thereby payable.

Hospital based sleep, as well as non hospital based sleep clinics shall be credentialed with the qualification listed in the Documentation Requirements below and shall meet the following criteria for HST/ PM/ or OOF testing:

- Physicians shall document the face to face clinical evaluation in a detailed narrative note in their charts, done prior to the testing being done.
- The notes must clearly indicate the patient has a high likelihood of having moderate to severe sleep apnea;
- This increased likelihood is evidenced by symptoms and physical examination documented in the note;
- That no comorbidities exist that are contraindications to HST/PM/OOF testing.

*PM is not appropriate for the diagnosis of OSA in patients with significant comorbid medical conditions or comorbid sleep disorders that may degrade the accuracy of PM, including, but not limited to, moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure.*

- For patients unable to be studied in the sleep laboratory when such a study is not possible by virtue of immobility, safety, or critical illness.
- For follow-up studies when diagnosis has been established by standard polysomnography and therapy and there is a material change in patients symptoms or complaints, again in the patient with no comorbid conditions. May also be indicated to monitor the response to non-CPAP treatments for sleep apnea.
- When initiation of treatment is urgent and standard polysomnography is not readily available.

**Types of Monitors:**

1. Type 1: full attended polysomnography (≥ 7 channels) in a laboratory setting
2. Type 2: full unattended polysomnography (≥ 7 channels)
3. Type 3: limited channel devices (usually using 4–7 channels)
4. Type 4: 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 sleep lab facility or attended in a sleep lab facility.
5. Sleep testing device measuring three or more channels that include actigraphy, oximetry, and peripheral arterial 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.

All HST apparatus must be applied by an experienced sleep technologist meeting the criteria listed in the Documentation Requirements below for the specific localities and therefore require a face to face meeting
for application and education.

A follow-up visit to review test results should be performed for all patients undergoing out of facility testing such as HST, or PM in the sleep facility authorized to order such testing. Negative or technically inadequate HST/PM tests in patients with a high pretest probability of moderate to severe OSA should prompt in-laboratory polysomnography.

Neither in facility polysomnography nor HST, PM, OOF testing is a covered service for Medicare beneficiaries for general screening of asymptomatic populations.

All reasonable and necessary diagnostic tests given for the medical conditions listed above are covered if the criteria are met. Because it is not reasonable and necessary, diagnostic testing that is duplicative of previous testing performed by the attending physician, to the extent that the results are still pertinent, is not covered.

At a minimum, HST/PM/OOF must record airflow, respiratory effort, and blood oxygenation. The airflow, effort, and oximetric biosensors conventionally used for in-laboratory PSG should be used in HST/PM. See above descriptions of monitor types.

WatchPAT 100 device was listed as a covered device by the FDM but does not meet the criteria for recording of airflow, respiratory effort and blood oxygenation and therefore is not considered for coverage in this LCD. Our review also found that actigraphy was not a sufficiently accurate substitute measure of sleep time to recommend its routine use. This device can be used for documentation of coverage of CPAP by NCD but the coverage of interpretation will not be paid separately for reason already stated.

A follow-up visit to review test results should be performed for all patients undergoing PM in the sleep facility authorized to order such testing. Negative or technically inadequate HST/PM tests in patients with a high pretest probability of moderate to severe OSA should prompt in-laboratory polysomnography.

Neither in house polysomnography nor HST/PM/OOF testing is a covered service for Medicare beneficiaries for general screening of asymptomatic populations.

**Coverage of Therapeutic Services**

Sleep disorder clinics may at times render therapeutic as well as diagnostic services. Therapeutic services may be covered in a hospital outpatient setting or in a freestanding facility or when supervised by same provided they meet the pertinent requirements for the particular type of services and are reasonable and necessary for the patient, and are performed under the direct personal supervision of a physician.

**Other Comments**

For claims submitted to the contractor: This coverage determination also applies within states outside the primary geographic jurisdiction with facilities that have nominated we will process their claims.

Bill type codes only apply to providers who bill these services to the contractor.

Limitation of liability and refund requirements apply when denials are based on medical necessity. The provider/supplier must notify the beneficiary in writing, prior to rendering the service, if the provider/supplier is aware that the test, item or procedure may not be considered medically necessary by Medicare. The limitation of liability and refund requirements do not apply when the test, item or procedure is statutorily excluded, has no Medicare benefit category or is rendered for screening purposes. In these instances it is recommended, although not required, that the provider notify the beneficiary in writing with a Notice of Exclusion of Medicare Benefits (NEMB).

For outpatient settings other than CORFs, references to "physicians" throughout this policy include non-physicians, such as nurse practitioners, clinical nurse specialists and physician assistants. Such non-physician practitioners, with certain exceptions, may certify, order and establish the plan of care for Polysomnography and Sleep Study services as authorized by State law. (See Sections 1861[s][2] and 1862[a][14] of Title XVIII of the SSA; 42 CFR, Sections 410.74, 410.75, 410.76 and 419.22; 58 FR 18543, April 7, 2000.)
Coding Information

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.

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99999</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

CPT/HCPCS Codes

This policy does not take precedence over the Correct Coding Initiative (CCI). Consult current correct coding guidelines for applicable specific code combinations or reductions in payment due to specific codes billed.

Please refer to the current CPT book for full descriptions.

The following CPT/HCPCS codes are covered per the above coverage criteria:

<table>
<thead>
<tr>
<th>CPT/HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95782</td>
<td>Polysom &lt;6 yrs 4/&gt; paramtrs</td>
</tr>
<tr>
<td>95783</td>
<td>Polysom &lt;6 yrs cpap/bilvl</td>
</tr>
<tr>
<td>95800</td>
<td>Slp stdy unattended</td>
</tr>
<tr>
<td>95801</td>
<td>Slp stdy unatnd w/anal</td>
</tr>
<tr>
<td>95805</td>
<td>Multiple sleep latency test</td>
</tr>
<tr>
<td>95806</td>
<td>Sleep study unatt&amp;resp efft</td>
</tr>
<tr>
<td>95807</td>
<td>Sleep study attended</td>
</tr>
<tr>
<td>95808</td>
<td>Polysom any age 1-3&gt; param</td>
</tr>
<tr>
<td>95810</td>
<td>Polysom 6/&gt; yrs 4/&gt; param</td>
</tr>
<tr>
<td>95811</td>
<td>Polysom 6/&gt; yrs cpap 4/&gt; parm</td>
</tr>
<tr>
<td>G0398</td>
<td>Home sleep test/type 2 Porta</td>
</tr>
<tr>
<td>G0399</td>
<td>Home sleep test/type 3 Porta</td>
</tr>
<tr>
<td>G0400</td>
<td>Home sleep test/type 4 Porta</td>
</tr>
</tbody>
</table>

The following CPT/HCPCS codes are NOT covered per the above coverage criteria:

<table>
<thead>
<tr>
<th>CPT/HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95999</td>
<td>Neurological procedure</td>
</tr>
</tbody>
</table>

ICD-9 Codes that Support Medical Necessity

95805

<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>278.03</td>
<td>OBESITY HYPOVENTILATION SYNDROME</td>
</tr>
<tr>
<td>327.42</td>
<td>REM SLEEP BEHAVIOR DISORDER</td>
</tr>
<tr>
<td>327.43</td>
<td>RECURRENT ISOLATED SLEEP PARALYSIS</td>
</tr>
<tr>
<td>347.00 - 347.01</td>
<td>NARCOLEPSY, WITHOUT CATAPLEXY - NARCOLEPSY, WITH CATAPLEXY</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>347.10 - 347.11</td>
<td>Narcolepsy in conditions classified elsewhere, without cataplexy - Narcolepsy in conditions classified elsewhere, with cataplexy</td>
</tr>
<tr>
<td>95806, 95800, 95801, 95807, 95808, 95810, 95811, G0398, G0399, G0400</td>
<td>Narcolepsy, without cataplexy - Narcolepsy, with cataplexy</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>607.84*</td>
<td>IMPOTENCE OF ORGANIC ORIGIN</td>
</tr>
<tr>
<td>780.51</td>
<td>INSOMNIA WITH SLEEP APNEA, UNSPECIFIED</td>
</tr>
<tr>
<td>780.53</td>
<td>HYPERSOMNIA WITH SLEEP APNEA, UNSPECIFIED</td>
</tr>
<tr>
<td>780.55</td>
<td>DISRUPTION OF 24 HOUR SLEEP WAKE CYCLE, UNSPECIFIED</td>
</tr>
<tr>
<td>780.56</td>
<td>DYSFUNCTIONS ASSOCIATED WITH SLEEP STAGES OR AROUSAL FROM SLEEP</td>
</tr>
<tr>
<td>780.57</td>
<td>UNSPECIFIED SLEEP APNEA</td>
</tr>
<tr>
<td>780.58</td>
<td>SLEEP RELATED MOVEMENT DISORDER, UNSPECIFIED</td>
</tr>
</tbody>
</table>

*ICD-9-CM code 607.84 requires proper documentation establishing medical necessity

**Diagnoses that Support Medical Necessity**

N/A

**ICD-9 Codes that DO NOT Support Medical Necessity**

Any ICD-9-CM code not listed as covered in the “ICD-9 Codes that Support Medical Necessity” section of this policy.

**ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation**

**Diagnoses that DO NOT Support Medical Necessity**

N/A

**Other Information**

**Documentation Requirements**
1. All centers billing sleep studies must maintain proper certification/ accreditation documentation as defined in the Indications and Limitations, which include:

2. Accreditation of sleep centers to include—AASM, Joint Commission, or ACHC.

3. All Sleep Studies, whether in a facility, portable monitoring, Home Sleep Testing, or Out Of Facility testing shall be supervised and interpreted by appropriate physician with training in this area. Acceptable Board Certifications include American Board of Sleep Medicine or the American Board of Medical Specialties with a certification in Sleep Medicine.

4. Appropriate technical personnel credentialing include:
   a. Board of Registered Polysomnographic Technologist (BRPT):
      - Certified Polysomnographic Technician (CPSGT),
      - Registered Polysomnography Technologist (RPSGT), and
   b. National Board of Respiratory Care (NBRC):
      - Certified Respiratory Therapist-Sleep Disorders Specialist (CRT-SDS)
      - Registered Respiratory Therapist – Sleep Disorders Specialist (RRT-SDS), and
   c. American Board of Sleep Medicine (ABSM)
      - Registered Sleep Technologist (RST)

5. The patient is to be evaluated by a physician prior to ordering of test. When billing for a sleep disorder test, the ordering physician's national identification number must be indicated on the claim form and the order kept on record.

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

7. If more than two nights of testing are claimed, medical documentation must justify the medical necessity for the additional test(s) should it be requested.

8. Studies may be performed in a freestanding center that is a direct extension of a physician's office or in an Independent Diagnostic Testing Facility (IDTF with restrictions as listed above.

9. In order for HST/PM/or OOF Testing to be covered, all criteria listed above must be met.

10. Medical Records must be available upon request.

Appendices
N/A

Utilization Guidelines
N/A

Sources of Information and Basis for Decision
Adopting the Trispan Legacy LCD L28542
CMS Manual System Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, section 70.
Kryger MH, Roth T, Dement WC, eds. Principles and Practice of Sleep Medicine. 2nd ed. Philadelphia: WB
CMS Manual System Pub. 100-03, Medicare National Coverage Determinations, Chapter 1, Part 4, section 240.4.
Final Decision Memo on CPAP therapy dated March 13, 2008.
The following clinical practice parameters and reviews issued by the American Academy of Sleep Medicine, as published in the journal SLEEP.
Practice Parameters for the Treatment of Narcolepsy: An Update for 2000, published June 2001 in SLEEP.
Sadeh A, Hauri P, Kripke DF, Lavie P. The Role of Actigraphy in the Evaluation of Sleep Disorders. SLEEP


DME MAC Information Link related to the 12 week home CPAP trail requirements.
http://www.cignagovernmentservices.com/jc/index.html

**Novitas Solutions, Inc. – JH Local Coverage Determination (LCD) Consolidation Narrative Justification – Most Clinically Appropriate LCD**

LCDs Compared:
L28542, Outpatient Sleep Studies, Pinnacle, Louisiana, Mississippi - A
L31185, Outpatient Sleep Studies, Pinnacle, Louisiana, Arkansas - B
L31183, Outpatient Sleep Studies, Pinnacle, Arkansas - A
DL31099, Outpatient Sleep Studies, Pinnacle
L28640, Polysomnography and Sleep Studies, TrailBlazer, TX, CO, NM, OK, Indian Health Service, ESRD, RHC, WPS legacy, - A/B

CMD Rationale:
Pinnacle has an extensive indication and limitation section. PBSI and TrailBlazer have diagnosis to procedure code monitoring. The TrailBlazer policy includes guidelines on split night services; however, the extensive discussion in the limitation and indication section of the Pinnacle LCD is more important.

Retain L31185 for JH. L31185 is the most clinically appropriate LCD.

**Advisory Committee Meeting Notes**

N/A

**Start Date of Comment Period**

N/A

**End Date of Comment Period:**

N/A

**Start Date of Notice Period**

06/28/2012
### Revision History

**Revision History Number**
6

**Revision History Explanation**

<table>
<thead>
<tr>
<th>Date</th>
<th>Policy #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/01/2013</td>
<td>(Revision History #6)</td>
<td>Multiple reconsideration requests were received to expand accreditation requirements, technical support accreditation requirements, clarify language about Home Sleep Testing vs Portable Monitoring, expand language on Split Night Testing, and to add clarification on whether the face to face meeting was needed before studies are to be performed. These changes required multiple changes throughout the document. Redundant language was removed as recognized. LCD revised for dates of service on and after 01/01/2013 to reflect the annual CPT/HCPCS code updates. The following code descriptor(s) have been revised: 95808, 95810, and 95811. The following code(s) have been added: 95782 and 95783.</td>
</tr>
<tr>
<td>11/19/2012</td>
<td>(Revision History #5)</td>
<td>Per CMS Change Request (CR) 7812, this LCD has been updated with the original effective date of 11/19/2012 to add the Novitas Jurisdiction H Part B MAC Contract Numbers 04112, 04212, 04312, and 04412 for Colorado Part B, New Mexico Part B, Oklahoma Part B, Texas Part B, Indian Health Service (IHS)/Tribal/Urban Indian Providers Part B, and Veterans Affairs (VA) Part B. No other changes were made to this LCD.</td>
</tr>
<tr>
<td>10/29/2012</td>
<td>(Revision History #4)</td>
<td>Per CMS Change Request (CR) 7812, this LCD has been updated with the original effective date of 10/29/2012 to add the Novitas Jurisdiction H Part A MAC Contract Numbers 04911, 04111, 04211, 04311, and 04411 for Colorado Part A, New Mexico Part A, Oklahoma Part A, Texas Part A, Indian Health Service (IHS)/Tribal/Urban Indian Providers Part A, and Veterans Affairs (VA) Part A. No other changes were made to this LCD.</td>
</tr>
<tr>
<td>10/22/2012</td>
<td>(Revision History #3)</td>
<td>LCD original effective date of 10/22/2012 for Mississippi Part B.</td>
</tr>
<tr>
<td>08/20/2012</td>
<td>(Revision History #2)</td>
<td>LCD original effective date of 08/20/2012 for Arkansas Part A, Louisiana Part A and Mississippi Part A.</td>
</tr>
<tr>
<td>08/13/2012</td>
<td>(Revision History #1)</td>
<td>LCD original effective date of 08/13/2012 for Arkansas Part B and Louisiana Part B. LCD posted for notice on 06/28/2012.</td>
</tr>
</tbody>
</table>

### Reason for Change

*Revisions due to CPT/HCPCS changes, reconsideration request*

### Related Documents

This LCD has no Related Documents.

### LCD Attachments

There are no attachments for this LCD.