

Local Coverage Determination (LCD): Polysomnography and Other Sleep Studies (L36861)

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Contractor Information

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Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
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CMS National Coverage Policy

When the documentation does not meet the criteria for the service rendered, or the documentation does not

establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

CMS Pub. 100-8, *Program Integrity Manual*, Chapter 13, Section 5.1

CMS Publication *100-03 Medicare National Coverage Determination (NCD) Manual*) Chapter 1, Section 240.4.1 Sleep Testing for Obstructive sleep Apnea (OSA) (Effective March 3, 2009) and Section 240.4 Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (Effective March 13, 2008)

CMS Publication *100-02 Medicare Benefit Policy* Chapter 6, Section 50 Sleep Disorder Clinics

CMS Publication *100-02, Medicare Benefit Policy Manual*, Chapter 15, Section 70 Sleep Disorder Clinics

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

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

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Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Sleep Studies and 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.

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 which 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 100-02 Medicare Benefit Policy Manual, Chapter 15, Section 70)

Polysomnography Testing

Polysomnography (PSG) includes sleep staging, which requires items 1 through 3 below. Polysomnography is defined to minimally include, but is not limited to, the following:

1. A 1-4 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, submental 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.

A. Criteria for Coverage of Diagnostic 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 clinic is either affiliated with a hospital or is under the direction and control of physicians. 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.

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 stay is considered an integral part of these tests.

- **Sleep Apnea** - *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% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation. 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, the carrier will require persuasive medical evidence justifying the medical necessity for the additional test (CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 70).

1. Obstructive Sleep Apnea (OSA) is the collapse of the oropharyngeal walls and the obstruction of airflow occurring during sleep.

CMS PUB 100-03 NCD Chapter 1, Section 240.4.1 – Sleep Testing for Obstructive Sleep Apnea (OSA) finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA.

a. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.

- The most comprehensive is designated Type I attended facility based polysomnography (PSG), which is considered the reference standard for diagnosing OSA. Attended facility based polysomnogram is a comprehensive diagnostic sleep test including at least electroencephalography (EEG), electro-oculography (EOG), electromyography (EMG), heart rate or electrocardiography (ECG), airflow, breathing/respiratory effort, and arterial oxygen saturation (SaO₂) furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed.
- Overnight PSG is the conventional diagnostic test for OSA. The American Thoracic Society and the American Academy of Sleep Medicine have recommended supervised PSG in the sleep laboratory over 2 nights for the diagnosis of OSA and the initiation of continuous positive airway pressure (CPAP).

b. Type II sleep testing devices are 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 monitors have a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, breathing/respiratory effort, SaO₂)-this type of device monitors sleep staging, so AHI can be calculated).

c. Type III sleep testing devices are 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 monitors have a minimum of 4 monitored channels including ventilation or airflow (at least two channels of respiratory movement or respiratory movement and airflow), heart rate or ECG, and oxygen saturation.

D. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are 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 may measure one, two, three or more parameters but do not meet all the criteria of a higher category device.
- Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are 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.

2. 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 three sleep naps. If more than three sleep naps are claimed; persuasive medical evidence justifying the medical necessity for the additional test(s) [will be required]. (CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 70).

- The diagnosis of narcolepsy is usually confirmed by an overnight sleep study (polysomnography) followed by a multiple sleep latency test (MSLT). MSLT involves several 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.
- 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.
 - Repeat polysomnography 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 initiation of therapy or confirmation of the efficacy of prescribed therapy is needed; **or**
 - If the results were inconclusive or ambiguous. Initial polysomnography and MSLT occasionally fail to identify narcolepsy.

3. Impotence – will not be addressed in this LCD. See CMS Publication *100-02, Medicare Benefit Policy Manual*, Chapter 15, Section 70 for coverage of impotence.

4. 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.

C. Split- Night Studies

1. For Continuous Positive Airway Pressure (CPAP) titration, a split-night study (initial diagnostic polysomnogram followed by CPAP titration during polysomnography on the same night) is an alternative to one full night of diagnostic polysomnography, followed by a second night of titration for the treatment of obstructive sleep apnea (OSA) if the following criteria are met.

Continuous Positive Airway Pressure (CPAP) 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).
2. A positive test for OSA is established if either of the following criteria using the Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) are met:
 - AHI or RDI greater than or equal to 15 events per hour with a minimum of 30 events;
 - or
 - AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or

insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

The AHI is equal to the average number of episodes of apnea and hypopnea per hour. The RDI is equal to the average number of respiratory disturbances per hour.

If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing is at least the number of events that would have been required in a 2-hour period.

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

D. Follow-up polysomnography or a cardio-respiratory sleep study is indicated for the following conditions:

- To evaluate the response to treatment (CPAP, oral appliances or surgical intervention);
- 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 symptomatic again despite 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.

E. Home Sleep Testing

- The physician services related to home sleep testing are covered for the purpose of testing a patient for the diagnosis of obstructive sleep apnea 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 has sufficient training and experience to reliably perform the service.
(See Physician requirements below)
- A home sleep test is covered only when it is performed in conjunction with a comprehensive sleep evaluation and in patients with a high pretest probability of moderate to severe obstructive sleep apnea.
- Home sleep testing is not covered for persons with comorbidities (moderate to severe pulmonary disease, neuromuscular disease or congestive heart failure)
- Home Sleep studies are only covered for the diagnosis of Obstructive Sleep Apnea. They are not covered for any other sleep disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders or narcolepsy) or for screening asymptomatic persons.

F. Physician and Technician Requirements for Sleep Studies and Polysomnography Testing:

1. The physician performing the service must meet one of the following:

a. be a diplomate of the American Board of Sleep Medicine (ABSM);

OR

b. has a Sleep Certification issued by **ONE** of the following Boards:

American Board of Internal Medicine (ABIM),

American Board of Family Medicine (ABFM),

American Board of Pediatrics (ABP),

American Board of Psychiatry and Neurology (ABPN),

American Board of Otolaryngology (ABOto),

American Osteopathic Board of Neurology and Psychiatry (AOBNP),

American Osteopathic Board of Family Medicine, (AOBFP)
American Osteopathic Board of Internal Medicine, (AOBIM)
American Osteopathic Board of Ophthalmology and Otorhinolaryngology (AOBOO);

OR

c. be an active physician staff member of a credentialed sleep center or laboratory that have active physician staff members meeting the criteria above in **a** or **b**.

2. Technician Credentials

The technician performing the service must meet one of the following:

- American Board of Sleep Medicine (ABSM),
Registered Sleep Technologist (RST);
- Board of Registered Polysomnographic Technologists (BRPT),
Registered Polysomnographic Technologist (RPSGT)
- National Board for Respiratory Care (NBRC)
Certified Pulmonary Function Technologist (CPFT)
Registered Pulmonary Function Technologist (RPFT)
Certified Respiratory Therapist (CRT)
Registered Respiratory Therapist (RRT)

G. Sleep Center or Laboratory Credentials (this is any site or place of service other than patient's home where sleep studies or recordings are performed)

- The sleep facility credentials must be from the American Academy of Sleep Medicine (AASM), inpatient or outpatient;

OR

- The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sleep specific credentials for Ambulatory care sleep centers.

OR

- Accreditation Commission for Health Care (ACHC)
 - All centers billing sleep studies must maintain proper certification documentation as defined above.
 - The sleep clinic must be affiliated with a hospital or be under the direction and control of a physician (MD/DO), even though the diagnostic test may be performed in the absence of direct physician supervision. This information must be documented and available upon request.
 - *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 the pertinent requirements for the particular type of services and are reasonable and necessary for the patient, and are performed under the direct supervision of a physician (CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 70, D. Coverage of Therapeutic Services)*

Non-covered Services

A. 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.

B. Actigraphy Testing:

Actigraphy measures movement of a limb. It can be measured as part of a sleep test but will not be paid for separately.

C. Polysomnography or a MSLT is not covered in the following situations:

1. for the diagnosis of patients with chronic insomnia;
2. to preoperatively evaluate a patient undergoing a laser assisted uvulopalatopharyngoplasty without clinical evidence that obstructive sleep apnea is suspected;
3. 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 symptoms suggest a diagnosis of obstructive sleep apnea, polysomnography is considered medically necessary);
4. in cases where seizure disorders have not been ruled out;
5. in cases of typical, uncomplicated, and non-injurious parasomnias when the diagnosis is clearly delineated;
6. for patients with epilepsy who have no specific complaints consistent with a sleep disorder;
7. for patients with symptoms suggestive of the periodic limb movement disorder or restless leg syndrome unless symptoms are suspected to be related to a covered indication;
8. for the diagnosis of insomnia related to depression;
9. 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).

Summary of Evidence

N/A

**Analysis of Evidence
(Rationale for Determination)**

N/A

General Information

Associated Information

Other Requirements

Polysomnography should be performed in a facility based sleep laboratory and not in the home or a mobile facility.

Narcolepsy symptoms should be severe enough to interfere with a patient's well-being and health.

If more than two nights of testing are performed, documentation justifying the medical necessity for the additional test(s) must be available in the patient's medical record.

Home sleep testing should be performed in conjunction with a comprehensive sleep evaluation and in patients with a high pretest probability of moderate to severe obstructive sleep apnea.

The following parameters must be monitored and documented:

- Start time and duration of day/night of study.
- Total sleep time, sleep efficiency, number/duration of awakenings.
- For tests involving sleep staging: time and percent time spent in each stage;
- For tests monitoring sleep latency or maintenance of wakefulness testing: latency to both Non-Rapid Eye Movement (NREM) and Rapid Eye Movement (REM) sleep.
- Individual sub-test sleep latencies, mean sleep latency and the number of REM occurrences on Multiple Sleep Latency Test (MSLT).
- Respiratory patterns including type (central/obstructive/periodic), number and duration, effect on oxygenation, sleep stage/body position relationship, and response to any diagnostic and /or therapeutic maneuvers.
- Cardiac rate/rhythm and any effect of sleep-disordered breathing on EKG.
- Detailed behavioral observations.

- EEG or EMG abnormalities.

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.

The routine use of more than one PSG to titrate CPAP therapy would not be considered reasonable and necessary. If more than one CPAP titration PSG is claimed, persuasive medical evidence justifying the medical necessity for the additional tests may be requested.

95805 MSLT- includes all the naps done in a single day. Only one (1) unit of service should be submitted.

Sources of Information

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9. Other Medicare Contractors LCDs

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
12/01/2019	R3	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
12/01/2019	R2	<p>12/01/2019:At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p> <p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD</p>	<ul style="list-style-type: none"> Provider Education/Guidance Revisions Due To Code Removal
10/01/2017	R1	<p>DATE (08/24/2017): At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p> <p>Effective 10/1/2017, LCD is revised to add ICD-10-CM codes: F51.3; F51.4</p>	<ul style="list-style-type: none"> Creation of Uniform LCDs With Other MAC Jurisdiction

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57697 - Billing and Coding: Polysomnography and Other Sleep Studies
A55491 - Response to Comments: Polysomnography and Other Sleep Studies
LCD(s)
DL36861
- (MCD Archive Site)

Related National Coverage Documents

N/A

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