Clinical Policy: Facility-based Sleep Studies for Obstructive Sleep Apnea

Reference Number: CP.MP.248
Date of Last Revison: 10/24

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Polysomnography (PSG) is the continuous and concurrent monitoring and recording of various physiological and pathophysiological parameters of sleep that includes physician evaluation, interpretation and dissemination. PSG is performed to diagnose various sleep disorders and evaluate the response to treatments such as continuous positive airway pressure (CPAP).[6] This policy establishes the medical necessity requirements for facility-based PSG, split-night studies, and bi-level and continuous positive airway pressure (CPAP/BiPAP) titration for suspected obstructive sleep apnea (OSA).

The policy criteria are derived from a combination of the American Academy of Sleep Medicine (AASM) guidelines[15,24], CMS local coverage determinations[6], and systematic reviews [4,5,7,10,11,20,23,26,27,28,29,30,31,32,33] which state that while PSG is currently considered the gold standard diagnostic test for OSA, home sleep apnea testing (HSAT) is an alternative method used and may be less costly and more efficient in some adult populations.[24] Indications not sourced from one of the reference types above are offered as supplemental options for meeting criteria in addition to those noted by AASM guidelines, local coverage determinations and systematic reviews.

Many HSAT devices have been validated against standard PSG, typically by testing the same patient with both modalities in the sleep laboratory. The sensitivity and specificity appear to be high in populations considered by sleep specialists to be at high risk of uncomplicated, moderate to severe OSA on the basis of clinical symptoms, assuming there are no comorbid medical disorders or other suspected sleep disorders.[11]

In addition to increased member/enrollee convenience, the main clinical advantage for HSAT is that sleep data can be obtained over several nights of sleep in the comfort of the member/enrollee's home rather than one night in a laboratory setting where the member/enrollee may not sleep for prolonged periods.

Given the performance of home sleep testing versus facility-based testing and the potential for medically appropriate members/enrollees to more closely replicate a typical night of sleep during home testing, as well as the criteria's consistency with AASM guidelines, this policy represents a favorable balance of benefits versus risks.

Note: For criteria applicable to Medicare plans, please see MC.CP.MP.248 Facility-based Sleep Studies for Obstructive Sleep Apnea.

Note: For suspected central sleep apnea, please refer to nationally recognized clinical decision support tools.

Policy/Criteria

I. It is the policy of non-Medicare health plans affiliated with Centene Corporation® that initial polysomnography (PSG) or a split-night study in a facility for evaluation of obstructive sleep apnea (OSA) for members/enrollees ≥ 18 years of age is **medically necessary** when meeting all of the following criteria:

A. Member/enrollee has suspected OSA[5];
B. Portable or home sleep apnea testing (HSAT) is not appropriate due to one or more of the following:
   1. Portable/HSAT services are not available[5];
   2. Member/enrollee is unable to properly operate or tolerate home study equipment and another individual is not available to assist[5];
   3. Previous HSAT results are negative or inadequate for diagnosis of suspected OSA[24];
   4. Previous HSAT results are negative or inadequate for autotitration of positive airway pressure (APAP) for suspected OSA[24];
   5. Chronic opioid use[24];
   6. Low pretest probability of OSA (normal BMI (<30), normal airway (Mallampati score 1 to 2), no snoring, and normal neck circumference (less than 17 inches in biological males, and less than 16 inches in biological females). Note: HSAT has a lower sensitivity for detection of OSA, making a facility PSG more appropriate in the presence of a low pretest probability of OSA[24,29];
   7. Member/enrollee works in a mission-critical function and falling asleep at work would have a major negative impact (e.g. airline pilots, bus drivers, taxi drivers, ride-sharing drivers, truck drivers, train operators, police, security, military posts, astronauts)[4,24];
   8. Member/enrollee has a BMI of ≥ 50 kg/m^2;
   9. **Both** of the following:
      a. Member/enrollee has documentation of one or more of the following risk factors:
         i. Moderate to severe chronic pulmonary disease[24;]
         ii. Congestive heart failure as evidenced by New York Heart Association (NYHA) class III or IV.[6,24,30,31]
         Note: See Table 1 below for NYHA classifications;
         iii. History of ventricular fibrillation or sustained ventricular tachycardia in the absence of an implanted defibrillator;
         iv. Neurologic or neuromuscular disease (e.g., stroke with significant residual effects, epilepsy, Parkinson's disease, spina bifida, myotonic dystrophy, amyotrophic lateral sclerosis)[6,24];
         v. Concern for presence of non-respiratory sleep disorder(s) that require evaluation or interfere with HSAT (e.g. disorders of central hypersomnolence, parasomnias, sleep related movement disorders, severe insomnia)[24];
         vi. Hypoventilation syndrome[24];
      b. Member/enrollee has signs or symptoms suggestive of OSA as evidenced by all of the following[24]:
         i. Daytime sleepiness[10];
         ii. Two or more of the following[24]:
            a) Habitual loud snoring;

b) Observed apnea or awakening with gasping or choking;
c) Diagnosis of hypertension.

II. It is the policy of non-Medicare health plans affiliated with Centene Corporation that repeat facility-based polysomnography (PSG) or split-night study (after an initial PSG or split-night study) for evaluation of OSA for members/enrollees ≥ 18 years of age is **medically necessary** when meeting all of the following:
A. All of the criteria in section I.B are met;
B. The requested study and any previous studies amount to two or less per rolling year[6];
C. Any of the following:
1. Oral appliance has been adjusted for fit and requires assessment of efficacy[6];
2. A change of device is needed due to intolerance of current device[6];
3. Assessment of whether positive airway pressure (PAP) treatment settings need to be changed (including but not limited to continued symptoms despite adherent use: at least four hours/night for 70% of nights over a 30-day period)[34];
4. Significant weight loss (≥10%) in a member/enrollee using PAP to determine if it can be discontinued[6,35];
5. Member/enrollee has had significant weight gain (≥10%) or recurrent symptoms and a repeat study will help inform whether PAP should be reinstituted[6];
6. Postoperative assessment of efficacy of surgery to treat OSA after upper airway surgical procedures[6];
7. Remote history of OSA and not on PAP with a need to re-establish diagnosis and/or initiate CPAP;
8. Suspicion of obstructive sleep apnea due to new signs or symptoms (e.g., weight gain accompanied by symptoms, new nocturia) in member/enrollee with previous negative study;
9. Signs, symptoms and strong clinical suspicion of OSA in member/enrollee with a negative study at least six months previous.[24]

III. It is the policy of non-Medicare health plans affiliated with Centene Corporation that facility-based titration of CPAP/BiPAP for evaluation of OSA for members/enrollees ≥ 18 years of age is **medically necessary** when meeting one of the following:
A. Meets criteria in section I for facility-based sleep study and has not attempted a home-based study for titration of APAP[16,26];
B. Diagnosed with OSA during HSAT and there is evidence or documentation of failure of an APAP trial including, but not limited to, downloaded compliance data.[24]

IV. It is the policy of health plans affiliated with Centene Corporation that there is insufficient evidence to support the use of actigraphy testing alone for diagnosis of obstructive sleep apnea as its effectiveness has not been established.[6]

Table 1: NYHA Classifications of Heart Failure	
Classification	**Characteristics**
Class I	Patients with cardiac disease but without the resulting limitations in physical activity. Ordinary activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain
Class II	Patients with heart disease resulting in slight limitations of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain
Class III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.
Class IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. The symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.

Background

Sleep-disordered breathing consists of several distinct disorders including obstructive sleep apnea (OSA), central sleep apnea (CSA), both with and without Cheyne-Stokes respiration, and sleep-related hypoventilation and hypoxemia.[2,3] Sleep apnea, a serious and potentially dangerous sleep disorder in which breathing repeatedly stops and starts, is divided into two main types, OSA and CSA. [4,5,6 7] The most common form of sleep apnea, OSA, is characterized by the partial or complete collapse of the upper airway during sleep, which causes symptoms such as excessive daytime sleepiness, gasping, snorting, loud snoring, and interrupted breathing.[4,5]

The International Classification of Sleep Disorders defines OSA as five or more predominantly obstructive respiratory events per hour in the presence of symptoms or certain comorbidities; or by 15 or more predominantly obstructive respiratory events per hour in asymptomatic patients.[4] Global estimates suggest that 936 million people between the ages of 30 and 69 years old have been diagnosed with mild to severe OSA and 425 million people with moderate to severe OSA.[4]

A detailed sleep history and examination accompanied by validated screening tools such as the Epworth Sleepiness Scale or STOP-Bang questionnaire, assist with the identification of patients with sleep-disordered breathing.[8] However, sleep testing is necessary for diagnostic confirmation.[8]

OSA should be suspected when a patient presents with excessive daytime sleepiness, snoring and choking, or gasping during sleep, especially in the presence of high-risk factors like advanced age and obesity, and in those with a male reproductive system. Additional complications related to OSA include refractory hypertension, atrial fibrillation, nocturnal angina, dysrhythmias, congestive heart failure, stroke, and transient ischemic attacks.[4, 9,10]

Polysomnography (PSG) is a comprehensive sleep study that monitors several physiologic components relevant to the assessment of sleep-disordered breathing such as sleep stage,

respiratory flow, respiratory effort, pulse oximetry and ventilation.[2,12] PSG results are interpreted by the reviewing clinician and treatment recommendations are made based on the recorded signals, results of scoring, and clinical history.[13] PSG tests can be used as a part of the diagnosis of a variety of additional sleep disorders including sleep-related movement disorders, narcolepsy, and certain parasomnias.[13] They are also used for titration of positive airway pressure and to assess the adequacy of ongoing therapy.[12,14]

PSG is conducted as a full-night study or split night study. A full night study involves monitoring the patient overnight, and if OSA is diagnosed, a return to the facility for PAP titration is sometimes necessary. A split-study involves monitoring of the patient's sleep pattern for the first part of the night, and if OSA is diagnosed, PAP titration is initiated the second part of the night.[4]

Home sleep apnea testing (HSAT) may be an appropriate, less stressful option for select patients with a high pretest probability of moderate to severe uncomplicated OSA, provided there is no suspicion of non-respiratory sleep disorders (e.g., narcolepsy, severe insomnia, parasomnias, movement disorders); no significant cardiorespiratory disease (e.g., COPD, asthma, CHF); they are not a mission-critical worker (e.g., airline pilot, bus driver, truck driver, astronaut); and a sleep expert is available to interpret the results.[4,5,12,15,16]

The most common HSAT devices currently used are classified as sleep monitoring devices of type 3 and type 4. Type 3 is preferred to type 4 because of the additional number of variables measured- four to seven versus one to three variables. The AASM considers home monitoring devices adequate when a minimum of the following sensors are included: nasal pressure, chest and abdominal respiratory inductance plethysmography, oximetry, or peripheral artery tone (PAT), actigraphy, oximetry.[4,11,17]

Studies have demonstrated the validity of HSAT results when compared to facility-based PSG. They note high sensitivity and specificity in populations at high risk of moderate to severe OSA based on clinical symptoms and in the absence of significant comorbidities that affect sleep or non respiratory sleep disorders.[4,11,17]

Advantages of HSAT include the convenience of testing at home and cost effectiveness.[11] The primary disadvantage of HSAT is that fewer physiologic variables are measured when compared with facility-based PSG, which can increase the likelihood for false-negative results. For most patients with suspected mild OSA, facility-based PSG in a is preferred since HSAT may lead to the under detection of sleep-related events in this population.[4,11]

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage.

Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT codes that support coverage

CPT®* Codes	Description
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist

CPT codes that do not support coverage

CPT®* Codes	Description
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Specialist reviewed.	01/23	01/23
Edited revision log entry from 1/23 to state "specialist reviewed" instead of "internal specialist reviewed." Changed title to "Facility-Based Sleep Studies for Obstructive Sleep Apnea." Updated description to include facility-based PSG, split-night studies and titration. Changed "sleep center" studies to "facility-based" studies throughout policy. Expanded scope of policy statement I. to include split-night studies. Clarified in I.B.3. that the titration was APAP. In I.B.5, added note about decreased sensitivity of HSAT in the presence of low probability of OSA. Added I.B.6. and I.B.7. as factors indicating that facility testing: mission-critical workers and BMI >50. Removed indication in I.B. for sleep center PSG performed simultaneously with CPAP titration in split-night study as the criteria now applies to split-night studies. Specified in I.B.8.a.i.a)1) that the nocturnal oxygen use is chronic and continuous. In I.B.8.a.ii.a), specified that pulmonary congestion has associated limiting dyspnea symptoms. In I.B.8.a.ii.b), removed option for left ventricular EF and instead referred to NYHA heart failure classification table. In I.B.8.a.iv., specified that the residual effects from stroke must be significant. In I.B.8.a.v., added parasomnia as an example of a complex sleep disorder. In B.8.b.ii.c), changed "resistant hypertension" to "refractory hypertension." In B.8.b.v., changed desaturation value to 88% from 90%.	03/23	03/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Added criteria sections II. and III. for repeat facility-based PSG/split-night studies and facility-based titration. Added code 95811.		
Revised criteria III.B. by removing requirement to meet criteria for facility-based sleep study and rewording failed APAP trial statement.	06/23	06/23
Corrected I.B.8.a.i. to require either continuous, chronic nocturnal oxygen use or moderate to severe pulmonary function impairment instead of both.	08/23	08/23
Annual review. Updated description and included "Notes". Added non-Medicare to all policy statements. Added superscript citations throughout policy. In I.B.8.a. added "documentation". Updated I.B.8.a.i. to "Moderate to severe, chronic pulmonary disease". Removed criteria I.B.8.a.i.a) and b). Updated I.B.8.a.ii. to "Congestive heart failure...". Updated I.B.8.a.v. to "Concern for significant non-respiratory sleep disorder(s)...". Added I.B.8.a.vi "Hypoventilation syndrome". Updated I.B.8.b.ii to "Daytime sleepiness...". Added I.B.8.b.ii.a "Habitual loud snoring". Removed I.B.8.b.iv. "Significant oxygen desaturation...". Updated III.A. to "Meets criteria in section I...". Removed III.C and D. for central sleep apnea. References reviewed and updated. Internal and external specialist reviewed.	01/24	01/24
Annual review. Description updated with no impact on criteria. Minor rewording in Criteria I., I.A., and I.B.3. with no impact to criteria. Changed I.B.3 into two indications in I.B.3 and 4 for clarity. Updated wording in Criteria I.B.8.a.v. and added addition of disorders that interfere with HSAT. Removed "moderate to-to-high-risk" verbiage in Criteria I.B.8.b. and updated outline of this criteria. Removed Epworth Sleepiness Scale criteria from I.B.8.b.i. Added Criteria I.B.8.b.ii.c) which states, "Diagnosis of hypertension." Minor rewording in Criteria II. with no impact to criteria. References reviewed and updated. Reviewed by internal specialist.	10/24	10/24

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program

approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take

precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.