FEP 2.01.18 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Summary
Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. Medical management of OSA may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous positive airway pressure (CPAP) during sleep.

FDA REGULATORY STATUS
A variety of oral appliances have been cleared for marketing clearance by U.S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of snoring and mild to moderate sleep apnea, including the Narval CC™, Lamberg SleepWell Smartrusion, 1st Snoring Appliance, Full Breath Sleep Appliance, PM Positioner, Snorenti, Snorex, Osap, Desra, Elastomeric Sleep Appliance, Snoremaster Snore Remedy, Snore-no-More, Napa, Snoar™ Open Airway Appliance, and The Equalizer Airway Device. FDA product code: LQZ.

A number of various CPAP devices have received clearance through the 510(k) process since 1977. BiPAP devices were first cleared for marketing by FDA in 1996. FDA product codes: BZD, MNT.

In 2010, a nasal expiratory resistance valve (PROVENT®, Ventus Medical) received clearance for marketing by FDA through the 510(k) process for the treatment of OSA. The Winx™ system received marketing clearance in 2012.

POLICY STATEMENT

Home/Unattended Sleep Study

Home/unattended sleep study testing is considered investigational in children younger than 18 years of age.
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Home/unattended (unsupervised) sleep study testing (HST) may be considered medically necessary for adult patients who are at high risk for obstructive sleep apnea (OSA). This includes:

- Absence of health conditions that might alter ventilation or requiring alternative treatment including:
  - Central sleep apnea
  - Heart failure
  - Chronic pulmonary disease
  - Obesity hypoventilation syndrome
  - Neuromuscular disorders with sleep-related symptoms, injurious or potentially injurious parasomnias, or narcolepsy
  - Screening tool in patients who are scheduled for bariatric surgery.

- The device used for HST has a minimum of 4 recording channels that includes:
  - Airflow
  - EKG or heart rate
  - Oxygen saturation level
  - Respiratory movement

Auto-adjusting positive airway pressure (APAP) may be considered medically necessary for the titration of pressure in adult patients with clinically significant OSA defined as those who have:

- An Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of at least 15 events per hour, or
- An AHI or RDI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

Repeated unattended (unsupervised) home sleep studies with a minimum of 4 recording channels (including oxygen saturation, respiratory movement, airflow, and ECG/heart rate) may be considered medically necessary in adult patients under the following circumstances:

- To assess efficacy of surgery or oral appliances/devices; OR
- To reevaluate the diagnosis of OSA and need for continued continuous positive airway pressure (CPAP), eg, if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued.

Facility/Laboratory Attended Polysomnography (PSG) Sleep Study

Supervised polysomnography (PSG) performed in a sleep laboratory may be considered medically necessary in patients with a moderate/high pretest probability of OSA in the following situations:

1. Pediatric patients (ie, <18 years of age); OR
2. When patients do not meet criteria for an unattended home sleep study as described above OR
3. A previous home study failed to establish the diagnosis of OSA in a patient with a high pretest probability of OSA; OR
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4. A previous home study was technically inadequate; OR

5. Failure of resolution of symptoms or recurrence of symptoms during treatment; OR

6. To reevaluate the diagnosis of OSA and need for continued CPAP, eg, if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued; OR

7. When testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy (see evidence review 2.01.99); OR

8. Presence of a comorbidity that might alter ventilation or decrease the accuracy of a home sleep study, including, but not limited to heart failure, neuromuscular disease, chronic pulmonary disease, or obesity hypoventilation syndrome.

A repeated supervised PSG performed in a sleep laboratory may be considered medically necessary in patients who meet criteria for an in-laboratory PSG and under the following circumstances:

1. To initiate and titrate CPAP in adult patients who have:
   - An AHI or RDI of at least 15 per hour, OR
   - An AHI or RDI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

Note: A split-night study, in which moderate to severe OSA is documented during the first portion of the study using PSG, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines section for criteria to perform a split-night study).

2. To initiate and titrate CPAP in children:
   - In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 10 or more may be considered severe.

3. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices

Supervised or unattended home sleep studies that do not meet the above criteria are not medically necessary.

The use of an abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies is considered investigational.

Multiple sleep latency testing is considered not medically necessary in the diagnosis of OSA.

**Medical Management**

CPAP may be considered medically necessary in adult or pediatric patients with clinically significant OSA.

Bilevel positive airway pressure (BiPAP) or APAP may be considered medically necessary in patients with clinically significant OSA AND who have failed a prior trial of CPAP or for whom BiPAP is found to be
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more effective in the sleep lab.

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in adult patients with clinically significant OSA under the following conditions:

- OSA, defined by an AHI or RDI of at least 15 per hour or an AHI or RDI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension, AND
- A trial with CPAP has failed or is contraindicated, AND
- The device is prescribed by a treating physician, AND
- The device is custom-fitted by qualified dental personnel, AND
- There is absence of temporomandibular dysfunction or periodontal disease

Note: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for patients with severe OSA, as oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-moderate OSA. Therefore, it is particularly important that patients with severe OSA should have an initial trial of CPAP and that all reasonable attempts are made to continue treatment with CPAP, prior to the decision to switch to an oral appliance.

Nasal expiratory positive airway pressure and oral pressure therapy devices are considered investigational.

POLICY GUIDELINES

Risk Factors for OSA
Although not an exclusive list, patients with all 4 of the following symptoms are considered to be at high risk for obstructive sleep apnea (OSA):

- habitual snoring;
- observed apneas;
- excessive daytime sleepiness;
- a body mass index (BMI) greater than 35

If no bed partner is available to report snoring or observed apneas, other signs and symptoms suggestive of OSA (eg, age of the patient, male gender, thick neck, craniofacial or upper airway soft tissue abnormalities, or unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; however, at the present time, risk assessment is based primarily on clinical judgment.

The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender) and has been shown to have 97% sensitivity and a negative predictive value of 96% (specificity of 33%) for the identification of patients with severe OSA (Apnea/Hypopnea Index [AHI] score >30). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is not adequate for the diagnosis of OSA. Therefore, a follow-up polysomnography (PSG) or home sleep study would still be required to confirm or exclude a diagnosis of OSA.

OSA in Children
The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a body mass index greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AH1 greater than 1.5 is considered abnormal (an AH1 score of ≥10 may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. CPAP
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is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

Bariatric Surgery Patients
Screening for OSA should be performed routinely in patients scheduled for bariatric surgery, due to the high prevalence of OSA in this population. The optimal screening approach is not certain. An in-laboratory PSG or home sleep study is the most accurate screening method. Some experts recommend a symptom based screening instrument, followed by PSG in patients who exceed a certain threshold, as an alternative to performing PSG in all patients. It should be noted that there is a high prevalence of obesity hypoventilation syndrome in patients who are candidates for bariatric surgery. Therefore, obesity hypoventilation syndrome should be ruled out prior to home sleep testing in this population.

Multiple Sleep Latency Test
The multiple sleep latency test (MSLT) is an objective measure of the tendency to fall asleep in the absence of alerting factors, while the maintenance of wakefulness test (MWT) is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). The MSLT and MWT are not routinely indicated in the evaluation and diagnosis of OSA or in assessment of change following treatment with continuous positive airway pressure (CPAP). The MSLT may be indicated as part of the evaluation of patients with suspected narcolepsy to confirm the diagnosis (often characterized by cataplexy, sleep paralysis, and hypnagogic/hypnopompic hallucinations) or to differentiate between suspected idiopathic hypersomnia and narcolepsy. Narcolepsy and OSA can co-occur. Because it is not possible to differentiate the excessive sleepiness caused by OSA and narcolepsy, the OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.

Specialist Training
The medical professional who is interpreting a polysomnogram or home sleep study should have training in sleep medicine and should review the raw data from PSG and home sleep studies in order to detect artifacts and data loss. In addition, the treatment of patients diagnosed with OSA should be initiated and monitored by a professional with training in sleep medicine. It is important to monitor symptoms and adherence to positive airway pressure (PAP) treatment, eg, review of symptoms and device utilization between 30 and 90 days.

Split Night Studies
American Academy of Sleep Medicine (AASM) Practice Parameters indicate that a split-night study (initial diagnostic PSG followed by CPAP titration during PSG on the same night) is an alternative to 1 full night of diagnostic PSG followed by a second night of titration if the following 4 criteria are met:

a. An AHI of at least 40 is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI of 20 to 40, based on clinical judgment (eg, if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP level requirements, based on split-night studies, may be less accurate than in full-night calibrations.

b. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).

c. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM (NREM) sleep, including REM sleep with the patient in the supine position.

d. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder (SRBD) is confirmed, but criteria b and c are not met.

Categorization of Polysomnography and Portable Monitoring
There is not full correspondence between the CPT codes and the most current categorization scheme for
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the different types of studies. In the 2005 practice parameters of AASM, there are 4 types of monitoring procedures: type 1, standard attended in-lab comprehensive PSG; type 2, comprehensive portable PSG; type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of 4 or more channels of monitoring; and type 4, continuous single or dual bioparameters, consisting of 1 or 2 channels, typically oxygen saturation, or airflow. Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and PSG are often used interchangeably. CPT coding makes a distinction between sleep studies that do not include electroencephalographic (EEG) monitoring, and PSG, which includes EEG monitoring. PSG is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the patient’s home. Cardiorespiratory sleep studies without EEG may be called polygraphic studies and can either be attended or unattended by a technologist. A wide variety of portable monitors and proprietary automated scoring systems are being tested and marketed, but the optimum combination of sensors and scoring algorithms is currently unknown. Current recommendations are that the portable monitoring device have 4 channels (oxygen saturation, respiratory effort, respiratory airflow, and heart rate) and allow review of the raw data. Type IV monitors with fewer than 3 channels are not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional with training in sleep medicine in order to detect artifacts and data loss.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

The evidence for home sleep testing with type 3 monitors (those with ≥4 recording channels) in individuals who have suspected obstructive sleep apnea (OSA) includes randomized controlled trials (RCTs). Relevant outcomes are test accuracy and resource utilization. RCTs have reported that home sleep testing is noninferior to testing in the sleep lab. Current literature indicates that assessment of OSA should be by clinical evaluation and overnight monitoring, either by attended polysomnography (PSG) or by portable unattended home monitoring under qualified supervision and that this may be followed by a trial of auto-adjusting positive airway pressure (APAP) to evaluate efficacy and adjust pressure.

- Portable monitoring may be conducted in adult patients with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation.
- A positive portable monitoring study with at least 4 channels of recording, including arterial oxygen saturation, airflow and respiratory effort, has a high positive predictive value for OSA and can be used as the basis for a continuous positive airway pressure (CPAP) trial to determine efficacy of treatment.
- A negative portable monitoring study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or have a positive study but do not respond to CPAP should undergo further evaluation.
- Due to the probability of artifacts or loss of data, raw data from the portable monitoring device should be interpreted by a sleep specialist. Follow-up and review of the APAP trial is also needed.
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Additional study is needed to determine the most reliable types of devices and combinations of sensors.

Questions also remain about the specific training of the medical personnel required to diagnose OSA without increasing risk of misdiagnosis. Based on the current evidence, portable monitoring for diagnosis of OSA in adult patients who are at high risk for OSA improves outcomes, when clinical evaluation and follow-up is conducted by a medical professional experienced in the diagnosis and treatment of sleep disorders. The evidence is sufficient to determine qualitatively that the technology results in an improvement in health outcomes.

The evidence for limited channel home sleep testing (includes type 4 monitors and WatchPAT) in patients who have OSA includes studies on diagnostic accuracy. Relevant outcomes are test accuracy and resource utilization. A number of questions remain on the ability to detect clinically significant OSA without sensors for heart rate, respiratory effort, and airflow, along with oxygen saturation. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the novel OSA treatments (including expiratory positive airway pressure [EPAP] and oral therapy) in patients who have OSA includes 1 RCT, 1 nonrandomized controlled study, and case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. CPAP is the primary treatment for OSA. The evidence on EPAP devices in patients with OSA has been reported in several prospective case series and 1 industry-sponsored RCT. The main finding of the RCT was a decrease in Apnea/Hypopnea Index score with minor impact on oxygenation and Epworth Sleepiness Scale score. One comparative trial with historical controls was identified on use of a PAP-NAP study for patients with complex insomnia who are resistant to CPAP titration or use. Additional study is needed to evaluate the efficacy of this intervention with greater certainty. No evidence was identified on the oral therapy device. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Sleep Medicine

The patient selection criteria for a PSG or sleep study require an estimate of the pretest probability of OSA, based on the signs and symptoms of OSA. Ideally, one would like to know the necessity of a PSG (ie, with electroencephalography [EEG]) versus a sleep study (without EEG). A detailed analysis of these issues is beyond the scope of this review. However, in 1997 the American Sleep Disorders Association (now the American Academy of Sleep Medicine [AASM]) published practice parameters for PSG and related procedures; these were most recently updated in 2005. The guidelines suggested that patients had a 70% likelihood of having an AHI index of at least 10 if all of the following were present: habitual snoring, excessive daytime sleepiness, a body mass index greater than 35, and observed apneas. In 2005, full-night PSG was recommended for the diagnosis of sleep-related breathing disorders and for PAP titration in patients with a Respiratory Disturbance Index (RDI) of at least 15 per hour, or with an RDI of at least 5 per hour in a patient with excessive daytime sleepiness. For patients in the high-pretest probability stratification group, an attended cardiorespiratory sleep study (type 3 with respiratory effort, airflow, arterial oxygen saturation, and electrocardiogram [ECG] or heart rate) was considered an acceptable alternative to full-night PSG, provided that repeat testing with full-night PSG was permitted for symptomatic patients who had a negative cardiorespiratory sleep study finding.

Portable monitoring devices were addressed by a joint project of AASM, the American Thoracic Society, and the American College of Chest Physicians in 2003. In 2007 AASM issued revised guidelines for
the use of unattended portable monitors, recommending that portable monitors should minimally record airflow, respiratory effort, and blood oxygenation, with biosensors conventionally used for in-laboratory PSG, and that testing be performed by an experienced sleep technologist and scored by a board-certified sleep medicine specialist under the auspices of an AASM-accredited comprehensive sleep medicine program.

The 2005 AASM guidelines gave a recommendation of standard for PSG when a diagnosis of periodic limb movement disorder is considered because of complaints by the patient or an observer of repetitive limb movements during sleep and frequent awakenings, fragmented sleep, difficulty maintaining sleep, or excessive daytime sleepiness. PSG is not routinely indicated to diagnose or treat restless legs syndrome, except where uncertainty exists in the diagnosis.

Evidence-based guidelines on BiPAP, and APAP have been published by AASM. There was moderate clinical certainty that BiPAP was appropriate as an optional therapy in some cases in which high pressure is needed and the patient experiences difficulty exhaling against a fixed pressure or coexisting central hypoventilation is present. APAP was not recommended to diagnose OSA, for split-night studies or for patients with heart failure, significant lung disease such as chronic obstructive pulmonary disease, patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (eg, obesity hypoventilation syndrome), patients who do not snore, and patients who have central sleep apnea syndromes. Unattended APAP in patients without significant comorbidities was considered an option (uncertain clinical use). The guidelines indicated that patients being treated on the basis of APAP titration must have close clinical follow-up to determine treatment effectiveness and safety, especially during the first few weeks of PAP use, and a reevaluation and, if necessary, a standard CPAP titration should be performed if symptoms do not resolve or if the APAP treatment otherwise appears to lack efficacy.

In 2015, AASM and the American Academy of Dental Sleep Medicine (AADSM) published a Clinical Practice Guideline on the treatment of OSA and snoring with oral appliance therapy. AASM and AADSM provided a recommendation of “standard” that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patient with OSA who are intolerant of CPAP therapy or prefer alternative therapy. The quality of evidence was rated as moderate. "Guideline" recommendations were provided for the use of custom, titratable appliance over noncustom oral devices, that qualified dentists provide oversight, that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, and that patients return for periodic office visits with a qualified dentist and a sleep physician.

AASM published evidence-based guidelines for respiratory indications for PSG in children in 2011. "Standard" recommendations were made for the following: PSG in children should be performed and interpreted in accordance with the AASM Manual for the Scoring of Sleep and Associated Events; PSG is indicated when the clinical assessment suggests the diagnosis of OSA in children; children with mild OSA preoperatively should have clinical evaluation following adenotonsillectomy to assess for residual symptoms. If there are residual symptoms of OSA, PSG should be performed; PSG is indicated following adenotonsillectomy to assess for residual OSA in children with preoperative evidence for moderate to severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, and neurologic disorders; PSG is indicated for positive airway pressure titration in children with OSA.

American Academy of Pediatrics
The American Academy of Pediatrics (AAP) published a 2012 guideline on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting, which updates AAP’s 2002 guidelines. AAP recommends that all children/adolescents should be screened for snoring, and PSG should be performed in children/adolescents with snoring and symptoms/signs of OSA as listed in the guideline. If PSG is not available, an alternative diagnostic test or referral to a specialist may be considered (Option). The estimated prevalence rates of OSA in children/adolescents range from 1.2% to
5.7%. Adenotonsillectomy is recommended as the first line of treatment for patients with adenotonsillar hypertrophy, and patients should be reassessed clinically postoperatively to determine whether additional treatment is required. High-risk patients should be reevaluated with an objective test or referred to a sleep specialist. CPAP is recommended if adenotonsillectomy is not performed or if OSA persists postoperatively. Weight loss is recommended in addition to other therapy in patients who are overweight or obese, and intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The use of CPAP devices are covered under Medicare when ordered and prescribed by the licensed treating physician to be used in adults with OSA if either of the following criteria using the AHI or RDI are met:

- AHI or RDI of 15 events per hour or more, or
- AHI or RDI between 5 and 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.

AHI or RDI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of sleep using actual recorded number of hours of sleep (ie, the AHI or RDI may not be extrapolated or projected). 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.

In 2001, the Centers for Medicare and Medicaid Services (CMS; formerly Health Care Financing Administration), published a decision memorandum for CPAP that addressed the issue of how to define moderate to severe OSA as a guide to a coverage policy for CPAP. This review of the literature suggested that there is a risk of hypertension with an AHI greater than 15, and thus treatment is warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 and associated symptoms, the CMS document concluded that the data from 3 randomized controlled trials demonstrated improved daytime somnolence and functioning in those treated with CPAP.

In 2008, CMS expanded coverage of CPAP to include those beneficiaries with a diagnosis of OSA made with a combination of a clinical evaluation and unattended home sleep monitoring using a device with at least 3 channels. The coverage of CPAP would initially be limited to a 12-week period to identify beneficiaries diagnosed with OSA who benefit from CPAP. This is a change from prior coverage, which specified that PSG must be performed in a facility-based sleep study laboratory and not in a home or a mobile facility. CMS defines AHI as the average number of episodes of apnea and hypopnea per hour of sleep, while the RDI is equal to the average number of respiratory disturbances per hour of continuous monitoring. There is variability in the published medical literature about the definition of the events that constitute a respiratory disturbance, and for the purposes of this national coverage decision, a respiratory disturbance is defined in the context of the sleep test technology of interest and, for portable monitoring devices that do not measure AHI or RDI directly, does not require direct measurement of airflow. Effective for claims with dates of service on and after March 13, 2008, CMS determines that CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under the following situations:
1. The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.

2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.

3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
   a. attended PSG performed in a sleep laboratory; or
   b. unattended home sleep test with a type II home sleep monitoring device; or
   c. unattended home sleep test with a type III home sleep monitoring device; or
   d. unattended least 3 channels.

4. The sleep test must have been previously ordered by the beneficiary's treating physician and furnished under appropriate physician supervision.

5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criteria using the AHI or RDI are met:
   a. AHI or RDI greater than or equal to 15 events per hour, or
   b. AHI or RDI greater than or equal to 5 events 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.ended home sleep test with a type IV home sleep monitoring device that measures.

6. The AHI or RDI is calculated on the average number of events of 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 must be at minimum the number of events that would have been required in a 2-hour period.

7. 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.

8. Coverage with Evidence Development: Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1–7 cited here. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions
   a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and types II, III, and IV home sleep test in identifying subjects with OSA who will respond to CPAP?
   b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or types II, III, and IV home sleep test, does CPAP cause clinically meaningful harm? In March 2009, CMS issued the following national coverage decision (CAG-00405N) for the types of sleep testing devices that would be approved for coverage.
CMS 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:

1. 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.

2. A type II or type III sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.

3. A type IV sleep testing device measuring 3 or more channels, one of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.

A sleep testing device measuring 3 or more channels that include actigraphy, oximetry, and peripheral arterial tone is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.

REFERENCES


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## POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review. Numerous references added and reordered; Oral pressure therapy added as not medically necessary, clarification of a single night for a home sleep studies; clarification of adult patients in the statement on oral appliances; PAP-NAP studies considered not medically necessary; telemonitored home sleep studies addressed in Policy Guidelines.</td>
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<tr>
<td>July 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review, adding references 33, 34, 49, 56, and 57. No change to policy statement.</td>
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<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>Rationale revised; references 3, 10, 15, 52-53, and 55-56 added and some references removed; statement added that screening of bariatric surgery patients may be medically necessary; revised criteria for home sleep studies and in laboratory polysomnography</td>
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<tr>
<td>March 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review through October 12, 2015; References 29, 44, and 48 added. Policy statements on parasomnias and sleep-related movement disorders revised for consistency with policy 2.01.99 on polysomnography for non-respiratory sleep disorders.</td>
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<tr>
<td>March 2016</td>
<td>Update Policy</td>
<td>No changes to policy statement.</td>
</tr>
<tr>
<td>December 2016</td>
<td>Correction</td>
<td>Auto-adjusting positive airway pressure (APAP) may be considered medically necessary for the titration of pressure in adult patients with clinically significant OSA defined as those who have:</td>
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<tr>
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<td>In accordance with MPRM correction, RDI added to CPAP and intraoral appliance criteria.</td>
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