



## FEP Medical Policy Manual

### FEP 2.01.18 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

**Effective Policy Date: October 1, 2021**

**Original Policy Date: December 2011**

**Related Policies:**

- 2.01.73 - Actigraphy
- 2.01.99 - Polysomnography for Non-Respiratory Sleep Disorders
- 7.01.101 - Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

## Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

### Description

#### Description

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. Polysomnography and portable sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone (PAT), actigraphy, and oxygen saturation are established methods for diagnosing OSA. Other proposed methods of diagnosing OSA include limited channel home sleep monitors. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of continuous positive airway pressure (CPAP) during sleep. Novel treatments include nasal expiratory positive airway pressure (EPAP) and oral pressure therapy.

#### OBJECTIVE

The objective of this evidence review is to evaluate the evidence for established and novel methods of diagnosing and treating obstructive sleep apnea.

## POLICY STATEMENT

### Diagnosis

A single unattended (unsupervised) home sleep apnea test with a minimum of 3 recording channels with the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or alternatively peripheral arterial tone (PAT), oximetry and actigraphy may be considered **medically necessary** in adults who are at high-risk for obstructive sleep apnea (OSA) and have no evidence of a health condition that might alter ventilation or require alternative treatment, ie, central sleep apnea, heart failure, chronic pulmonary disease, obesity hypoventilation syndrome, neuromuscular disorders with sleep-related symptoms, injurious or potentially injurious parasomnias, or narcolepsy. The Policy Guidelines section defines high pretest probability.

A single unattended (unsupervised) home sleep apnea test with a minimum of recording channels as described above, may be considered **medically necessary** as a screening tool in patients who are scheduled for bariatric surgery and have no evidence of a health condition that might alter ventilation or require alternative treatment (see Policy Guidelines section).

Unattended home sleep studies are considered **investigational** in children (<18 years of age).

Repeated unattended (unsupervised) home sleep apnea test with a minimum of 3 recording channels with the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or alternatively PAT, oximetry and actigraphy, may be considered medically necessary in adults under the following circumstances:

1. To assess efficacy of surgery or oral appliances or devices; OR
2. To reevaluate the diagnosis of OSA and need for 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.

Supervised polysomnography (PSG) performed in a sleep laboratory may be considered **medically necessary** in patients with a moderate or 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 apnea test 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
4. A previous home study was technically inadequate; OR
5. Failure of resolution of symptoms or recurrence of symptoms during treatment; OR
6. 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
7. Presence of a comorbidity that might alter ventilation or decrease the accuracy of a home sleep apnea test, 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 the criteria above for an in-laboratory PSG under the following circumstances:

1. To initiate and titrate CPAP in adults 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 1 or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke);

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 or RDI of  $\geq 5$ ; OR
  - An AHI or RDI  $\geq 1.5$  in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.
3. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices.

Supervised or unattended home sleep apnea tests that do not meet the above criteria are considered **investigational**.

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 **investigational** in the diagnosis of OSA.

## Medical Management

Auto-adjusting positive airway pressure may be considered **medically necessary** for the titration of pressure in adults with clinically significant OSA defined as those who have:

- An AHI, RDI, or Respiratory Event Index (REI) of at least 15 events per hour, OR
- An AHI, RDI, or REI of at least 5 events per hour in a patient with 1 or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke); OR
- If there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued.

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

Clinically significant OSA in adults is:

- An AHI, RDI, or REI  $\geq 15$ , OR
- An AHI, RDI, or REI  $\geq 5$  in a patient with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

In pediatric patients,

- An AHI or RDI  $\geq 5$  OR
- An AHI or RDI  $\geq 1.5$  in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.

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

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

OSA, defined by an AHI, RDI, or REI of at least 15 events per hour or an AHI, RDI, or REI of at least 5 events per hour in a patient with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke), 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, because oral appliances have been shown to be less efficacious in patients with severe OSA than in patients with mild-to-moderate OSA. Therefore, it is particularly important that patients with severe OSA 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.

The use of CPAP, bi-level positive airway pressure, APAP, and intraoral appliances that do not meet the above criteria is considered **investigational** for the treatment of OSA.

The use of an abbreviated daytime sleep session for acclimation to CPAP (PAP-NAP) is considered **investigational**.

The use of a sleep positioning trainer with vibration is considered **investigational** for the treatment of positional OSA.

The use of daytime electrical stimulation of the tongue is considered **investigational** for the treatment of OSA.

Palate and mandible expansion devices are considered **investigational** for the treatment of OSA.

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

## POLICY GUIDELINES

### Specialist Training

Polysomnography (PSG) or home sleep apnea testing should be performed in appropriately selected patients and the test summary results reviewed by a physician who is trained in sleep medicine.

Medical professionals who interpret a polysomnogram or home sleep apnea test should be trained in sleep medicine and should review the raw data from PSG and home sleep apnea tests to detect artifacts and data loss.

Treatment of patients diagnosed with OSA should be initiated and monitored by a professional trained in sleep medicine. It is important to monitor symptoms and adherence to positive airway pressure (PAP) treatment (eg, review of symptoms and device utilization at 90 days with a minimum of 4 hours per night for at least 5 nights per week).

### Risk Factors for Obstructive Sleep Apnea

Although not an exclusive list, patients with all 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 kg/m<sup>2</sup>.

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, unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; at present, risk assessment is based primarily on clinical judgment.

The STOP-BANG questionnaire, a method developed for nonsleep specialists, assesses the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender), has been shown to have 97% sensitivity and 96% negative predictive value (specificity, 33%) for the identification of patients with severe OSA (Apnea/Hypopnea Index [AHI] >30 events per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is inadequate for the diagnosis of OSA. Therefore, a follow-up PSG or home sleep apnea test would still be required to confirm or exclude a diagnosis of OSA.

### Obstructive Sleep Apnea 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 BMI greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI or Respiratory Disturbance Index (RDI) greater than 1.5 events per hour is considered abnormal (an AHI or RDI 10 events per hour may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. Continuous positive airway pressure (CPAP) 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 apnea test 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 apnea testing in this population.

## Significant Weight change

There is no established threshold for significant change in weight. Studies have reported improvements in OSA with an average weight loss of 20 kg or 20% of body weight.

## 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 is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). The MSLT and maintenance of wakefulness test are not routinely indicated in the evaluation and diagnosis of OSA or in the assessment of change following treatment with CPAP. The MSLT may be indicated in 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 between the excessive sleepiness caused by OSA and by narcolepsy, OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.

## Split-Night Studies

American Academy of Sleep Medicine practice parameters (2005) have indicated 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:

1. An AHI of at least 40 events per hour is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI between 20 and 40 events per hour, 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.
2. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).
3. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM sleep, including REM sleep with the patient in the supine position.
4. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder is confirmed, but criteria 2 and 3 are not met.

## Categorization of Polysomnography and Portable Monitoring

Full correspondence does not exist between Current Procedural Terminology (CPT) codes and the most current categorization scheme for the different types of studies. The 2005 practice parameters from the American Academy of Sleep Medicine list 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 distinguishes 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. There are no specific codes for remotely monitored home sleep studies. They would likely be reported with the CPT code for the sleep study with the GT modifier ("via interactive audio and video telecommunications systems") appended. There is no CPT code for "unattended" PSG.

Cardiorespiratory sleep studies without EEG may be called polygraphic studies and can be attended or unattended by a technologist. CPT codes 95807 and 95806 distinguish polygraphic sleep studies that are attended or unattended, but there are no codes that distinguish between type 3 and type 4 sleep studies. 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, heart rate) and permit review of the raw data. Type 4 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 trained in sleep medicine 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).

### Weight Loss Programs

Weight loss is frequently recommended for obese patients with obstructive sleep apnea (OSA). Plans may want to review their policies on weight loss programs in general and determine whether such policies should apply to patients with OSA. In some instances, continuous positive airway pressure (CPAP) may also be recommended while the patient is in a weight loss program; if the weight loss program is successful, further therapy may be unnecessary. If the weight loss program is unsuccessful, and the patient does not tolerate CPAP (or auto-adjusting positive airway pressure [APAP] or bilevel positive airway pressure), surgical therapy may be considered.

## FDA REGULATORY STATUS

A variety of oral appliances have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for treatment of snoring and mild-to-moderate OSA, including the Narval™ CC, Lamberg Sleep Well Smartfusion, 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.

Various PAP devices have been cleared by the FDA through the 510(k) process since 1977. Bilevel positive airway pressure devices were first cleared for marketing in 1996. FDA product codes: BZD, MNT.

Novel devices for OSA diagnosis and treatment are described in Table 1.

**Table 1. Novel Devices for OSA Diagnosis and Treatment**

Device	Manufacturer	Description	FDA Marketing Clearance	FDA Product Code	Year
<b>Diagnosis</b>					
SleepImage System	MyCardio	Software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor to aid in the evaluation of sleep disorders.	K163696	MNR	2017
<b>Treatment</b>					
Provent	Ventus Medical	Nasal expiratory resistance valve.		OHP	2010
Winx™		Nasal expiratory resistance valve.		OZR	2012
mRNA Appliance	BioModeling Solutions	Expandable oral appliance for the treatment of snoring and mild-to-moderate OSA	K130067	LRK	2014

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NightBalance Lunox System	Philips	The positional sleep trainer is worn with an elasticized chest strap, and is intended to keep patients with positional obstructive sleep apnea from sleeping in the supine position.	K180608	MYB	2018
eXciteOSA	Signifier Medical Technologies	The device delivers neuromuscular stimulation during the day to strengthen the tongue in order to reduce snoring and mild sleep apnea. It is used for 20 minutes once a day for a period of 6-weeks, and once a week thereafter.	DEN200018	QNO	2021

FDA: Food and Drug Administration; OSA: obstructive sleep apnea

## RATIONALE

### Summary of Evidence

#### Diagnosis

For individuals who have suspected OSA who receive home sleep apnea testing with at least 3 recording channels, the evidence includes RCTs. Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. RCTs have reported that home sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone, actigraphy and oxygen saturation) is noninferior to testing in the sleep lab for adults with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation. A positive portable monitoring study with channels that include arterial oxygen saturation, airflow, and respiratory effort has a high positive predictive value for OSA and can be used as the basis for a CPAP trial to determine the 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. The evidence is sufficient to determine that the technology results in an I improvement in the net health outcome.

For individuals who have suspected OSA who receive limited channel home sleep apnea testing, the evidence includes studies on diagnostic accuracy. Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. The ability to detect clinically significant OSA without sensors for respiratory effort, airflow, and oxygen saturation, or alternatively without peripheral arterial tone, actigraphy and oxygen saturation, lacks support in the literature. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### Treatment

For individuals who have OSA who receive PAP devices or oral appliances, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and QOL. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. A diagnostic sleep study may be followed by a trial of APAP to evaluate the efficacy and adjust pressure. APAP or bilevel PAP may also be indicated if the patient is intolerant of CPAP. The evidence is sufficient to determine that the technology results in an I improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments (eg, palate expansion, EPAP, oral pressure therapy, tongue stimulation, supine vibration), the evidence includes RCTs, prospective single arm studies, and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed to evaluate this treatment. The evidence on nasal EPAP devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the AHI, with minor impact on oxygenation, and a decrease in ESS score. One small RCT with 22 patients found no benefit of an oral EPAP therapy device when added to an oral appliance. One comparative trial with historical controls and a retrospective chart review evaluated PAP-NAP to reduce resistance to CPAP titration or use. Additional study is needed to evaluate the efficacy of this intervention. Single arm studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is of uncertain. Several RCTs have been published with a sleep positioning device that vibrates when the individual is in a supine position. Drop-out rates were high and long-term compliance is unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### American Academy of Sleep Medicine

In 2017, the American Academy of Sleep Medicine (AASM) published clinical practice guidelines on diagnostic testing for adult OSA.<sup>45</sup> AASM provided the following recommendations (Table 2).

**Table 2. Recommendations on Diagnostic Testing for Adult OSA**

Recommendation Statement	SOR	QOE	Benefits vs Harms
We recommend that clinical tools, questionnaires, and prediction algorithms not be used to diagnose OSA in adults, in the absence of PSG or HSAT	Strong	Moderate	High certainty that harms outweigh benefits
We recommend that PSG, or HSAT with a technically adequate device, be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA.	Strong	Moderate	High certainty that benefits outweigh harms
We recommend that if a single HSAT is negative, inconclusive, or technically inadequate, PSG be performed for the diagnosis of OSA.	Strong	Low	High certainty that benefits outweigh harms
We recommend that PSG, rather than home sleep testing, be used for patients with significant cardiorespiratory disorder, potential respiratory muscle weakness, awake or suspected sleep hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.	Strong	Very low	High certainty that benefits outweigh harms
We suggest that, if clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for PSG be used for the diagnosis of OSA	Weak	Low	Low certainty that benefits outweigh harms
We suggest that when the initial PSG is negative, and there is still clinical suspicion for OSA, a second PSG be considered for the diagnosis of OSA.	Weak	Very low	Low certainty that benefits outweigh harms

HSAT: home sleep apnea testing; OSA: obstructive sleep apnea; PSG: polysomnography; QOE: quality of evidence; SOR: strength of recommendation.

The AASM considers a technically adequate home sleep apnea test (HSAT) device to incorporate "a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else PAT [peripheral arterial tone] with oximetry and actigraphy." The guidelines refer to the AASM Manual for the Scoring of Sleep and Associated Events for additional information regarding HSAT sensor requirements.

The AASM also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA.<sup>46</sup> The levels of recommendation are "standard" (generally accepted patient-care strategy, with a high degree of certainty; level 1 to 2 evidence), "guideline" (moderate degree of clinical certainty; level 2 to 3 evidence), or "option" (uncertain clinical use; insufficient or inconclusive evidence).

## Diagnosis

The AASM recommended that patients who are obese, retrognathic, hypertensive, or who complain of snoring or daytime sleepiness should be assessed for presence or absence as well as the severity of OSA using the following methods (standard):

- Sleep history assessment includes witnessed apneas, gasping/choking at night, excessive sleepiness, total sleep amount, nocturia, morning headaches, and decreased concentration and memory.
- Physical assessment includes evaluation of respiratory, cardiovascular, and neurologic systems and signs of upper respiratory narrowing.
- Objective testing, under an AASM-accredited program, and attended by trained technical personnel. The diagnosis of OSA is confirmed if the number of obstructive events (apneas, hypopneas plus respiratory event related to arousals) is greater than 15 events/hour or greater than 5 events/hour in a patient reporting any of the following: unintentional sleep episodes during wakefulness; daytime sleepiness, unrefreshing sleep; fatigue; insomnia; waking up breath holding, gasping, or choking; or a bed partner describing loud snoring, breathing interruptions, or both.
  - In laboratory polysomnography (standard) records electroencephalogram, electrooculogram, chin electromyogram, airflow, oxygen saturation, respiratory effort, and heart rate.
  - Home testing with portable monitors should at minimum, record airflow, respiratory effort, and blood oxygenation.

Treatment with positive airway pressure

- Continuous positive airway pressure (CPAP) is indicated for patients with moderate to severe OSA (Standard) and mild OSA (Option).
- Bilevel positive airway pressure can be considered in CPAP-intolerant patients (Consensus).
- Autotitrating positive airway pressure can be considered in CPAP-intolerant patients (Consensus).

Treatment with oral appliances (OA) is indicated for "patients with mild to moderate OSA, who prefer OAs to CPAP, or who do not respond to CPAP, or are not appropriate candidates for CPAP, or who fail CPAP ... (Guideline)."

- Mandibular repositioning appliance covers the upper and lower teeth.
- Tongue-retaining device holds the tongue in a forward position.

The AASM (2019) published a clinical practice guideline on the treatment of OSA with positive airway pressure (PAP) that was based on a systematic review of the evidence.<sup>11,12</sup> "A STRONG (ie, "We recommend...") recommendation is one that clinicians should follow under most circumstances. A CONDITIONAL recommendation (ie, "We suggest...") reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients."

The AASM provided strong recommendations for the following use of PAP therapy in adults:

- Use of PAP to treat OSA in adults with excessive sleepiness.
- That PAP therapy be initiated at home using APAP or in-laboratory PAP titration in adults with no significant morbidities.
- Use of CPAP or APAP for ongoing treatment of OSA.
- That clinicians provide educational interventions with the initiation of PAP.

The AASM provided conditional recommendations (suggest) for the following use of PAP therapy in adults:

- Use of PAP to treat OSA in adults with impaired sleep-related quality of life.
- Use of PAP to treat OSA in adults with comorbid hypertension.
- Use CPAP or APAP over BPAP in the routine treatment of OSA.
- That behavioral and/or troubleshooting interventions be given during the initial period of PAP therapy.
- That clinicians use telemonitoring during the initial period of PAP therapy.

The AASM and the American Academy of Dental Sleep Medicine (2015) published guidelines on the treatment of OSA and snoring with oral appliance therapy.<sup>25</sup> The 2 societies provided a recommendation of "standard" that sleep physicians consider prescription of oral appliance, rather than no treatment, for adults 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.

## American Academy of Pediatrics

The American Academy of Pediatrics (AAP; 2012) published guidelines 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 updated the AAP's 2002 guidelines.<sup>47,48</sup> AAP recommended that all children or adolescents be screened for snoring, and PSG is performed in children or adolescents with snoring and symptoms or 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 or adolescents ranged from 1.2% to 5.7%. Adenotonsillectomy was recommended as the first-line 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 was recommended if adenotonsillectomy was not performed or if OSA persisted postoperatively. Weight loss was 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.

## American Society of Metabolic and Bariatric Surgery

The American Society of Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA (reviewed in October 2015).<sup>49</sup> The guidelines noted that while some reports in the literature have recommended routine screening for OSA prior to bariatric surgery, other reports have suggested clinical screening only does not result in any increase in postoperative pulmonary complications after laparoscopic Roux-en-Y gastric bypass, and that most current surgical practices refer patients with clinical symptoms of OSA for PSG, but do not make this a routine preoperative test prior to bariatric surgery. The Society provided, based on the evidence in the literature to date, the following guidelines on OSA in the bariatric surgery patient and its perioperative management:

1. "OSA is highly prevalent in the bariatric patient population...."
4. [Patients with moderate to severe OSA] should bring their CPAP machines, or at least their masks, with them at the time of surgery and use them following bariatric surgery at the discretion of the surgeon.
7. Routine pulse oximetry or capnography for postoperative monitoring of patients with OSA after bariatric surgery should be utilized, but the majority of these patients do not routinely require an ICU [intensive care unit] setting.
8. No clear guidelines exist upon which to base recommendations for retesting for OSA following bariatric surgery...."

## American Academy of Otolaryngology-Head and Neck Surgery

In 2017, the American Academy of Otolaryngology-Head and Neck Surgery published a position statement on the treatment of obstructive sleep apnea.<sup>50</sup> The academy states that tonsillectomy and adenoidectomy is the first line treatment in pediatric OSA. In most adults, CPAP is the first line treatment. Surgical procedures may be considered when PAP therapy is inadequate.

## American Thoracic Society

The American Thoracic Society (2016) published a research statement on the long-term effects and treatment of mild OSA in adults.<sup>51</sup> The Society's systematic review concluded:

- Daytime sleepiness: subjective improvement with CPAP; unclear effect of non-CPAP therapies
- Quality of life: small improvements seen in different domains in different studies
- Neurocognition: treatment effects inconsistent.

## U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2017) reported on the evidence for screening for OSA in adults and concluded that "the current evidence is insufficient to assess the balance and harms of screening for obstructive sleep apnea (OSA) in asymptomatic adults. Evidence on screening tools to accurately detect persons in asymptomatic populations who should receive further testing and treatment of subsequently diagnosed OSA to improve health outcomes is lacking, and the balance of benefits and harms cannot be determined."[52,53](#).

## Medicare National Coverage

In 2001, the Centers for Medicare & Medicaid Services published a decision memorandum on CPAP that addressed how to define moderate-to-severe OSA as a guide to a coverage policy for CPAP. This review of the literature suggested there is a risk of hypertension with an AHI greater than 15 events per hour, and thus treatment would be warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 events per hour and associated symptoms, CMS 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 clinical evaluation and unattended home sleep monitoring using a device with at least 3 channels.[54,55](#) 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 was defined in the context of the sleep test technology of interest and, for portable monitoring devices that do not measure AHI or Respiratory Disturbance Index (RDI) directly, does not require direct measurement of airflow.

Effective in March 2008, CMS determined that CPAP therapy, when used in adults with OSA, would be considered reasonable and necessary in 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 clinical evaluation and a positive:
  1. attended PSG performed in a sleep laboratory; or
  2. unattended HST [home sleep test] with a Type II home sleep monitoring device; or
  3. unattended HST with a Type III home sleep monitoring device; or
  4. unattended HST with a Type IV home sleep monitoring device that measures at 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:
  1. AHI or RDI greater than or equal to 15 events per hour, or
  2. 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.
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 (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address 1 or more of the following questions:
1. 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 & IV HST in identifying subjects with OSA who will respond to CPAP?
  2. In Medicare aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Types II, III & IV HST, does CPAP cause clinically meaningful harm?"

In March 2009, CMS issued a national coverage decision (CAG-00405N) for the types of sleep testing devices that would be approved for coverage.<sup>56</sup> CMS found that the evidence was 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, 1 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.
4. Sleep testing devices measuring 3 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."

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Date	Action	Description
March 2016	Replace policy	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.
December 2016	Replace policy	No changes to policy statement.
April 2017	Replace policy	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. In accordance with MPRM correction, RDI added to CPAP and intraoral appliance criteria.
September 2017	Replace policy	Policy updated with literature review through April 25, 2017; references 27, 34, and 48-49 added. Investigational statement added on palate expansion devices.
September 2018	Replace policy	Policy updated with literature review through April 9, 2018; references 4, 24, and 40 added. Policy statements clarified that sleep studies may report the Respiratory Disturbance Index or Respiratory Event Index. Criteria for changes in weight or changes in symptoms were removed from the policy statement on in-laboratory polysomnography and added to the statement on auto-adjusting positive airway pressure. Clinically significant OSA was defined.
September 2019	Replace policy	Policy updated with literature review through April 16, 2019; references added. Terminology changed from home sleep study to home sleep apnea test. Devices that include a minimum of the following 3 sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or alternatively peripheral arterial tone with oximetry and actigraphy may be considered adequate for home sleep apnea testing for obstructive sleep apnea. Policy statements revised to include new terminology of home sleep apnea test and clarify that devices include a minimum of 3 sensors. The following policy statements were revised from "not medically necessary" to "investigational" to align with OPM guidance regarding 510(k) FDA regulatory status for medical devices: Supervised or unattended home sleep studies not meeting criteria; Multiple sleep latency testing in the diagnosis of OSA. New policy statement added: The use of CPAP, bi-level positive airway pressure, APAP, and intraoral appliances that do not meet the above criteria is considered investigational for the treatment of OSA.
September 2020	Replace policy	Policy updated with literature review through May 11, 2020; references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through May 6, 2021; references added. Investigational policy statements for sleep positioning trainer and daytime tongue stimulation device added. PAP-NAP statement moved from Diagnosis to Medical Management section of policy statement.

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