

# Protocol

## Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

(2018)

<b>Medical Benefit</b>		<b>Effective Date:</b> 12/01/20	<b>Next Review Date:</b> 09/21
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 03/07, 05/08, 11/08, 05/09, 03/10, 03/11, 03/12, 03/13, 03/14, 09/14, 05/15, 07/15, 07/16, 07/17, 07/18, 07/19, 09/19, 09/20	

### **Preauthorization is required.**

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### **RELATED PROTOCOLS**

Actigraphy

Polysomnography for Non-Respiratory Sleep Disorders

Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

<b>Populations</b>	<b>Interventions</b>	<b>Comparators</b>	<b>Outcomes</b>
Individuals: • With suspected obstructive sleep apnea	Interventions of interest are: • Home sleep testing with at least three recording channels	Comparators of interest are: • Polysomnography	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Resource utilization
Individuals: • With suspected obstructive sleep apnea	Interventions of interest are: • Limited channel home sleep apnea testing	Comparators of interest are: • In-laboratory polysomnography • Home sleep testing with at least three recording channels	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Resource utilization
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Positive airway pressure devices	Comparators of interest are: • Weight loss • Position therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Oral appliances	Comparators of interest are: • Continuous positive airway pressure therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Novel obstructive sleep apnea treatment (e.g., expiratory positive airway pressure, oral pressure therapy, palate expansion)	Comparators of interest are: • Continuous positive airway pressure therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

**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.

**SUMMARY OF EVIDENCE****DIAGNOSIS**

For individuals who have suspected OSA who receive home sleep apnea testing with at least three 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 a meaningful 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 the effects of the technology on health outcomes.

**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 a meaningful improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments (e.g., palate expansion, EPAP, oral pressure therapy), the evidence includes RCTs 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 comparative trial with historical controls used a PAP-NAP to

study patients with complex insomnia resistant to CPAP titration or use. Additional study is needed to evaluate with greater certainty the efficacy of this intervention. One small RCT with 22 patients found no benefit of an oral EPAP therapy device when added to an oral appliance. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### Additional Information

The policy statements focus on criteria for the diagnosis and treatment of sleep apnea for procedures considered standard of care and are based in part on evidence-based practice guidelines. In addition, clinical input was obtained on several occasions to assess, among other items, the sensors required for portable monitors, diagnosis and treatment of OSA in children, and screening of patients scheduled to undergo bariatric surgery. Informed by clinical input and clinical practice guidelines, testing is indicated for patients who are suspected of OSA, prior to bariatric surgery, for certain pediatric patients, and with type 4 monitors under certain circumstances.

## POLICY

### DIAGNOSIS OF SUSPECTED OBSTRUCTIVE SLEEP APNEA (OSA)

#### Home, Unsupervised Study

A home, unsupervised sleep study in patients >18 years of age is considered **medically necessary** if the following criteria are met:

- A. At least two (2) of the following must be present:
1. Observed apneas during sleep
  2. Frequent snoring or choking/gasping during sleep
  3. Excessive daytime sleepiness documented by history or with an Epworth Sleepiness Scale greater than ten
  4. Treatment resistant hypertension

OR

- B. One of the following is present:
1. Obesity with Body Mass Index (BMI) >35 kg/m<sup>2</sup>
  2. Patients scheduled for bariatric surgery
  3. STOP-BANG score of  $\geq 5$

AND

- C. None of the following contraindications for a home, unsupervised study are present:
1. History of significant arrhythmias, such as atrial fibrillation, periods of supraventricular or ventricular tachycardia, or bradyarrhythmias. The presence of occasional atrial or ventricular extra beats is not considered a significant arrhythmia.
  2. Congestive heart failure (Ejection Fraction (EF) <35% or NYHA Class III or IV)
  3. Moderate to severe COPD, as indicated by FEV1/FVC of <70% and FEV1 <80% of predicted value
  4. Oxygen dependence
  5. Suspected central sleep apnea

6. Suspected obesity-hypoventilation syndrome
7. Neuromuscular disorders with sleep related symptoms
8. Suspected insomnia, parasomnias, or narcolepsy
9. Periodic limb movements in sleep
10. Restless leg syndrome
11. Cognitive or physical impairment affected ability to use home sleep monitoring equipment
12. Failed or inadequate prior home, unsupervised sleep study.

A home, unsupervised sleep study is considered **not medically necessary** if above criteria are not met.

#### In-lab, Supervised Sleep Study

An in-lab, supervised sleep study is considered **medically necessary** if criteria A or B listed above for home, unsupervised studies are met and one of the contraindications listed above in Section C above is present.

An in-lab, supervised sleep study is considered **not medically necessary** if above criteria are not met.

#### CPAP TITRATION SLEEP STUDY

##### Home, Unsupervised Study

A home, unsupervised sleep study for CPAP titration using an auto-adjusting positive airway pressure (APAP) device is considered **medically necessary** in a person who has previously had a diagnostic home, unsupervised sleep study documenting clinically significant OSA as indicated by:

- An Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), or Respiratory Event Index (REI) of > 15 OR
- An AHI, RDI, or REI  $\geq 5$  in a patient with one or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

A home, unsupervised sleep study for CPAP titration is considered **not medically necessary** if above criteria are not met.

##### In-lab, Supervised Sleep Study

An in-lab, supervised sleep study for CPAP titration is considered **medically necessary** in a person who has previously had a diagnostic in-lab, supervised sleep study if the criteria above for a home, unsupervised study are met.

An initial in-lab split night sleep study is also considered **medically necessary** if severe OSA is identified within the first two hours of a diagnostic study.

An in-lab, supervised sleep study for CPAP titration is considered **not medically necessary** if above criteria for such a study are not met.

#### REPEAT SLEEP STUDIES

##### Home, Unsupervised Study

A repeat home, unsupervised sleep study is considered **medically necessary** if criteria for an initial diagnostic sleep study are met for the following circumstances:

- To assess efficacy of surgery or oral appliances or devices; OR

- To reevaluate the diagnosis of OSA and need for CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued.

A repeat home, unsupervised sleep study is considered **not medically necessary** if any of the circumstances listed above are not met.

#### In-lab, Supervised Sleep Study

A repeat in-lab, supervised sleep study is considered **medically necessary** if criteria for an initial diagnostic sleep study are met for the following circumstances:

- To assess efficacy of surgery or oral appliances or devices; OR
- To reevaluate the diagnosis of OSA and need for CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued OR
- For any patient (even if prior testing was a home, unsupervised sleep study) who requires titration for BiPAP because of a recurrence of symptoms or worsening of symptoms during treatment with CPAP.

A repeat in-lab, supervised sleep study is considered **not medically necessary** if any of the circumstances listed above are not met.

#### MEDICAL MANAGEMENT OF OSA

CPAP may be considered medically necessary in patients >18 years of age with clinically significant OSA, as defined by:

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

Bilevel positive airway pressure (BiPAP) 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:

- 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.

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.

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** for the treatment of OSA.

## EVALUATION AND MANAGEMENT OF OSA IN CHILDREN (&lt;18 YEARS OF AGE)

Diagnosis of Suspected Obstructive Sleep Apnea in Children

**NOTE:** Signs and symptoms of OSA in children are more non-specific than in adults. Medical necessity includes suspicion of OSA plus one or more of the findings listed below.

An in-lab, supervised sleep study is considered medical necessary in children <18 years of age when one (1) or more of the following are present in a child suspected of OSA:

- Frequent snoring ( $\geq 3$  nights/wk)
- Labored breathing during sleep
- Gasps/snorting noises/observed episodes of apnea
- Sleep enuresis (especially enuresis after six months of continence)
- Sleeping in a seated position or with the neck hyperextended
- Cyanosis
- Headaches on awakening
- Daytime sleepiness
- Attention-deficit/hyperactivity disorder
- Learning problems
- Physical examination findings:
  - Underweight or overweight
  - Tonsillar hypertrophy
  - Adenoidal facies
  - Micrognathia/retrognathia
  - High-arched palate
  - Failure to thrive
  - Hypertension

An in-lab, supervised sleep study is considered **investigational** in children <18 years of age when one (1) or more of the above signs and symptoms are not present in a child suspected of OSA.

A home, unsupervised sleep study is considered **not medically necessary** under all circumstances for children <18 years of age.

CPAP Titration Sleep Study in Children

An in-lab, supervised sleep study for CPAP titration for a child is considered **medically necessary** when a previously diagnostic sleep study documented clinically significant OSA as indicated by:

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

An in-lab, supervised sleep study for CPAP titration for a child is considered **not medically necessary** when the above criteria are not met.

### Repeat Sleep Studies in Children

A repeat in-lab, supervised sleep study for a child is considered **medically necessary** for the following circumstances:

- Evaluation for residual OSA in children with preoperative evidence for moderate to severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, and neurologic disorders.
- Evaluation for residual OSA in children with preoperative evidence for mild OSA if residual symptoms persist
- Follow-up on children on CPAP to determine whether pressure requirements have changed as a result of the child's growth and development, if symptoms recur while on PAP, or if additional or alternate treatment is instituted.

A repeat in-lab, supervised sleep study for a child is considered **not medically necessary** if the above circumstances are not met.

### Medical Management of OSA in Children

CPAP may be considered **medically necessary** in children <18 years of age with clinically significant OSA, as defined by:

- 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.

The use of CPAP that does not meet the above criteria is considered **investigational** for the treatment of OSA in children <18 year of age.

The use of APAP or BiPAP considered **investigational** for the treatment of OSA in children <18 year of age.

## **POLICY GUIDELINES**

The sleep study must have been previously ordered by the patient's treating physician (MD, DO, Dentist Certified in sleep medicine) and furnished under appropriate physician supervision.

### **SPECIALIST TRAINING**

Polysomnography 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 (e.g., review of symptoms and device utilization at 90 days with a minimum of four hours per night for at least five nights per week).

The diagnosis of a sleep disorder, as well as any resulting recommendation for treatment, must be made by a physician. Once a diagnosis of sleep apnea or a sleep related breathing disorder is established by a physician, a referral may be made to a dental sleep specialist to provide treatment. The role of a dentist is in assisting patients in the proper selection and fitting of an oral appliance, as well as in providing long term follow up care.

#### 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 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, (e.g., 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; 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 (**S**nore, **T**ired, **O**bserved apnea, **B**lood **P**ressure, **B**MI, **A**ge, **N**eck, **G**ender) and has been shown to have 97% sensitivity and a 96% negative predictive value (specificity, 33%) for the identification of patients with severe OSA (AHI greater than 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.

#### 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 BMI greater than the 90<sup>th</sup> percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI greater than 1.5 events per hour is considered abnormal (an AHI or RDI of ten or more events per hour may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. 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 (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 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 (AASM) Practice Parameters (2005) indicate that a split-night study (initial diagnostic PSG followed by CPAP titration during PSG on the same night) is an alternative to one full night of diagnostic PSG followed by a second night of titration if the following four criteria are met:

- a. An AHI of at least 40 events per hour is documented during a minimum of two 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 (e.g., 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 three 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

Full correspondence does not exist between CPT codes and the most current categorization scheme for the different types of studies. The 2005 practice parameters of the AASM, list four 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 four or more channels of monitoring; and type 4, continuous single or dual bio-parameters, consisting of one or two 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. 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 four channels (oxygen saturation, respiratory effort, respiratory airflow, heart rate), and permit review of the raw data. Type 4 monitors with fewer than three 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 in order to detect artifacts and data loss.

**MEDICARE ADVANTAGE**

## DIAGNOSIS

For Medicare Advantage, diagnostic testing as described below is considered **medically necessary** to establish a diagnosis of OSA:

1. Type I PSG when used to aid the diagnosis of OSA in patients who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. Type II or Type III sleep testing devices when used to aid the diagnosis of OSA in patients 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. Type IV sleep testing devices measuring three or more channels, one of which is airflow, when used to aid the diagnosis of OSA in patients 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 three or more channels that include actigraphy, oximetry, and peripheral arterial tone, when used to aid the diagnosis of OSA in patients 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.

## MEDICAL MANAGEMENT

A CPAP device is considered **medically necessary** when used in adults with OSA when the following criteria are met:

A positive diagnosis of OSA including a clinical evaluation and a positive:

- a. attended PSG performed in a sleep laboratory; or
- b. unattended HST with a Type II home sleep monitoring device; or
- c. unattended HST with a Type III home sleep monitoring device; or
- d. unattended HST with a Type IV home sleep monitoring device that measures at least three channels.

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

An initial 12-week period of CPAP is **medically necessary** in adult patients with OSA if either of the following criterion using the AHI or RDI are met (see Medicare Advantage Policy Guidelines):

- a. AHI or RDI greater than or equal to 15 events per hour, or
- b. AHI or RDI greater than or equal to five 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.

CPAP is initially limited to a 12-week period to identify patients diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently **medically necessary** only for those patients diagnosed with OSA who benefit from CPAP during this 12-week period.

The provider of CPAP must conduct education of the patient or caregiver (if caregiver is consistently available) prior to the use of the CPAP device to ensure that the patient or caregiver has been educated in the proper use of the device.

A single-level continuous positive airway pressure device is **medically necessary** for the treatment of OSA if criteria A – C are met:

- A. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea.
- B. The patient has a Medicare covered sleep test that meets either of the following criteria (1 or 2):
  - 1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
  - 2. The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
    - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
    - b. Hypertension, ischemic heart disease, or history of stroke.
- C. The patient and/or their caregiver has received instruction from the supplier of the device in the proper use and care of the equipment.

A bi-level respiratory assist device (RAD) without back-up rate is **medically necessary** for those patients with OSA who meet criteria A-C above, in addition to criterion D:

- D. A single-level continuous positive airway pressure device has been tried and proven ineffective\* based on a therapeutic trial conducted in either a facility or in a home setting.

\*Ineffective is defined as documented failure to meet therapeutic goals using a single-level continuous positive airway pressure device during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings).

A bi-level positive airway pressure device with back-up rate is **not medically necessary** if the primary diagnosis is OSA.

The term PAP (positive airway pressure) device will refer to both a single-level continuous positive airway pressure device and a bi-level respiratory assist device without back-up rate when it is used in the treatment of obstructive sleep apnea (OSA).

A PAP device for the treatment of OSA is considered **medically necessary** where the diagnosis of OSA is based upon a sleep test (Type I, II, III, IV, Other). An appropriate sleep test would be either a polysomnogram performed in a facility-based laboratory (Type I study) or a home sleep test (HST) (Types II, III, IV, Other) (see Medicare Advantage Policy Guidelines for information on HST). The test must be ordered by the patient's treating practitioner and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

**Medical appropriateness** of a PAP device beyond the first three months of therapy requires that, no sooner than the 31<sup>st</sup> day but no later than the 91<sup>st</sup> day after initiating therapy, the treating physician must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy. Clinical benefit is demonstrated by:

- 1. Face-to-face clinical re-evaluation by the treating practitioner with documentation that symptoms of obstructive sleep apnea are improved; and,
- 2. Objective evidence of adherence\*\* to use of the PAP device, reviewed by the treating practitioner.

If the physician re-evaluation does not occur until after the 91<sup>st</sup> day but the evaluation demonstrates that the patient is benefiting from PAP therapy as defined in criteria 1 and 2 above, continued coverage of the PAP device will commence with the date of that re-evaluation.

\*\*Adherence to therapy is defined as use of PAP greater than or equal to four hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.

Patients who fail the initial 12 week trial are eligible to re-qualify for a PAP device but must have both:

1. Face-to-face clinical re-evaluation by the treating practitioner to determine the etiology of the failure to respond to PAP therapy; and
2. Repeat sleep test in a facility-based setting (Type 1 study – see Medicare Advantage Policy Guidelines). This may be a repeat diagnostic, titration or split level night study.

If a CPAP device is tried and found ineffective during the initial three month home trial, substitution of a RAD does not change the length of the trial unless there is less than 30 days remaining in the trial period. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31<sup>st</sup> and 91<sup>st</sup> day following the initiation of CPAP.

If a CPAP device was used for more than three months and the patient was switched to a Respiratory Assist Devices (RAD), then the clinical re-evaluation would occur between the 31<sup>st</sup> and 91<sup>st</sup> day following the initiation of the RAD. There would also need to be documentation of adherence to therapy during the three month trial with the RAD.

If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies. Replacement after five years requires that there is a face-to-face evaluation by their treating practitioner that documents that the patient uses and has benefit from the PAP device.

A repeat Medicare covered sleep test is considered **medically necessary** to document the need for continued CPAP therapy if the available test results do not meet the current Medicare criteria for continued coverage.

#### ORAL APPLIANCES

A custom fabricated mandibular advancement oral appliance used to treat OSA is **medically necessary** if criteria A-D are met:

- A. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea testing.
- B. The patient has a Medicare-covered sleep test that meets one of the following criteria (1-3):
  1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
  2. The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
    - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
    - b. Hypertension, ischemic heart disease, or history of stroke; or,
  3. If the AHI is greater than 30 or the RDI is greater than 30 and meets either of the following (a or b):
    - a. the patient is not able to tolerate a positive airway pressure (PAP) device or
    - b. the treating physician determines that the use of a PAP device is contraindicated.
- C. The device is ordered by the treating physician following review of the report of the sleep test. (The physician who provides the order for the oral appliance could be different from the one who performed the clinical evaluation in criterion A.)

D. The device is provided and billed for by a licensed dentist (DDS or DMD).

Replacement of medically necessary oral appliances:

Oral appliances are eligible for replacement at the end of their five-year reasonable useful lifetime (RUL). These items may be replaced prior to the end of the five-year RUL in cases of loss, theft, or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). Replacement due to wear-and-tear as the result of everyday use will not be provided prior to the expiration of the five-year RUL.

A prefabricated oral appliance is considered **investigational**.

## MEDICARE ADVANTAGE POLICY GUIDELINES

### DEFINITIONS

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 two hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at a minimum the number of events that would have been required in a two-hour period.

A Type I sleep test is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with practitioner review, interpretation, and report. It is facility-based and must include sleep staging, which is defined to include a one to four lead electroencephalogram (EEG), and electrooculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

### DIAGNOSIS

An HST is performed unattended in the patient's home using a portable monitoring device. A portable monitoring device for conducting an HST must meet one of the following criteria:

1. Type II device – Monitors and records a minimum of seven (7) channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory movement/effort and oxygen saturation; or,
2. Type III device – Monitors and records a minimum of four (4) channels: two respiratory movement/effort, airflow, ECG/heart rate and oxygen saturation; or,
3. Type IV device – Monitors and records a minimum of three (3) channels one of which is airflow or,
4. Other – Devices that monitor and record a minimum of three (3) channels that include actigraphy, oximetry and peripheral arterial tone and for which there is substantive clinical evidence in the published peer-reviewed medical literature that demonstrates that the results accurately and reliably correspond to an AHI or RDI as defined above. This determination will be made on a device by device basis.

All patients who undergo a HST must, prior to having the test, receive instruction of how to properly apply a portable sleep monitoring device. This education must be provided by the entity conducting the HST and may not be performed by a DME supplier. Patient instruction can be by either face-to-face demonstration or by video or telephonic instruction, with 24 hour availability of qualified personnel to answer questions or troubleshoot issues with the device.

### GENERAL INFORMATION

For all non-hospital based facilities, the facility must have on file documentation that it is in compliance with the

criteria set by the American Sleep Disorders Association, the American Academy of Sleep Medicine or the Accreditation Commission for Health Care, Inc. Failure to supply such documentation may result in denial of the claim. Sleep studies performed in mobile sleep laboratories are not covered.

The sleep laboratory or testing facility must be affiliated with a hospital or be under the direction and control of a physician (MD/DO), even though the diagnostic test may be performed in the absence of direct physician supervision. The laboratory-physician director must be:

- Board-certified in sleep medicine (ABSM, i.e., Diplomate of, or board-eligible for, the American Board of Sleep Medicine); or
- Diplomate or board-eligible for an American Board of Medical Specialties (ABMS) approved board; or
- Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself, and only until the time of reporting of the first examination for which the physician is eligible; or
- An active staff member of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) the Accreditation Commission for Health Care, Inc. or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]).

HST scoring must be performed by an individual certified by the Board of Registered Polysomnographic Technologists as a Registered Polysomnographic Technologist (RPSGT), or equivalent, or by a polysomnographic technician under the supervision of a RPSGT, or Registered Respiratory Therapist-Sleep Disorder Specialist (RRT-SDS) or a Certified Respiratory Therapist-Sleep Disorder Specialist (CRT-SDS), or equivalent. RPSGTs, RRT-SDS, CRT-SDS and polysomnographic technicians must meet the standards for such individuals promulgated by the American Academy of Sleep Medicine Standards for Accreditation of Laboratories for Sleep Related Breathing Disorders, or by the Accreditation Commission for Health Care, Inc. Standards for Accreditation for Sleep Programs or by the National Board for Respiratory Care (NBRC) Inc. and be licensed or certified by the state in which they practice, if such licensure or certification exists. The laboratory physician must review the entire raw data recording for every patient studied.

*No aspect of an HST, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.*

## BACKGROUND

### OBSTRUCTIVE SLEEP APNEA

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This causes a drop in blood oxygenation and brief arousal and can occur as frequently as every minute throughout the night. The most common signs and symptoms in adults are snoring, excessive daytime sleepiness, and hypertension. Excessive daytime sleepiness may be subjective and is assessed by questionnaires such as the Epworth Sleepiness Scale, a short self-administered, questionnaire that asks patients how likely they are to fall asleep in different scenarios such as watching TV, sitting quietly in a car, or sitting and talking to someone. Daytime sleepiness is uncommon in young children with OSA. Symptoms in children may include disturbed sleep and daytime neurobehavioral problems. In otherwise healthy children, OSA is usually associated with adenotonsillar hypertrophy and/or obesity.

The hallmark of OSA is snoring. The snoring abruptly ceases during the apneic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. The sleep fragmentation associ-

ated with repeated sleep disruption can lead to impairment of daytime activity. Adults with OSA-associated daytime somnolence are thought to be at higher risk for collisions involving motorized vehicles (i.e., cars, trucks, heavy equipment), while OSA in children may result in neurocognitive impairment and behavioral problems.

OSA can also affect the cardiovascular and pulmonary systems.<sup>1</sup> For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This, in turn, can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile collisions related to daytime sleepiness. It is estimated that about 7% of adults have moderate or severe OSA, 20% have mild OSA, and the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease.<sup>1</sup>

### Diagnosis

The criterion standard for a diagnosis of sleep disorders is a polysomnogram performed in a sleep laboratory.<sup>2</sup> A standard polysomnogram includes electroencephalogram (EEG), submental electromyogram, and electrooculogram (to detect rapid eye movement sleep) for sleep staging. Polysomnography also typically includes electrocardiography and monitoring of respiratory airflow, effort, snoring, oxygen desaturation, and sleep position. An attended study ensures that the electrodes and sensors are functioning adequately and do not dislodge during the night. In addition, an attendant is able to identify severe OSA in the first part of the night and titrate continuous positive airway pressure (CPAP) in the second part of the night, commonly known as a “split-night” study. If successful, this strategy eliminates the need for additional polysomnography for CPAP titration.

Table 1. Definitions of Terms and Scoring Criteria for OSA

Terms	Definition
<b>Respiratory event</b>	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as two or more missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either >3% arterial oxygen desaturation or an arousal. Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or associated arousal.
RERA	Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea.
<b>Respiratory event reporting</b>	
AHI	The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep.
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available.
OSA	Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep.
Mild OSA	Adults: AHI or RDI of 5 to <15; Children: AHI $\geq$ 1.0 to <5
Moderate OSA	Adults: AHI or RDI of 15 to <30; Children: AHI of $\geq$ 5 to <10
Severe OSA	Adults: AHI or RDI $\geq$ 30; Children: AHI of $\geq$ 10
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.

Terms	Definition
<b>Positive airway pressure</b>	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP.
PAP	Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure.
PAP failure	Usually defined as an AHI >20 events per hour while using CPAP.
PAP intolerance	CPAP use for <4 hours per night for ≥5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA.

AHI: Apnea/hypopnea Index; APAP: auto-adjusting positive airway pressure; EEG: electroencephalogram; OSA: obstructive sleep apnea; PAP: positive airway pressure; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal; UARS: upper airway resistance syndrome.

Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as two or more missed breaths, regardless of its duration in seconds. In pediatric patients, an AHI greater than 1.5 events per hour is considered abnormal, and an AHI of 10 or more may be considered severe.

A variety of devices have been developed specifically to evaluate OSA at home. They range from portable full polysomnography systems to single-channel oximeters. Available devices evaluate different parameters, which may include oximetry, respiratory and cardiac monitoring, and sleep/wake activity, but most portable monitors do not record EEG activity.

#### Treatment

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure therapy (i.e., fixed CPAP, bilevel positive airway pressure, or auto-adjusting positive airway pressure) during sleep. This evidence review addresses established and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (BioModeling Solutions), Provent and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA.

Surgical management of OSA (i.e., adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in the Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome Protocol.

#### 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 Smartrusion, first 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.

In 2014, the mRNA Appliance® (BioModeling Solutions) was cleared for marketing by the FDA through the 510(k) process (K130067) for the treatment of snoring and mild-to-moderate OSA. FDA product code: LRK.

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.

In 2010, a nasal expiratory resistance valve (Provent®, Ventus Medical) was cleared for marketing by the FDA through the 510(k) process for the treatment of OSA. The Winx™ system received marketing clearance in 2012. FDA product codes: OHP, OZR.



In 2017, SleepImage System (MyCardio) was cleared for marketing by the FDA through the 510(k) process to aid in the evaluation of sleep disorders (K163696). The SleepImage System is considered software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor. FDA product code: MNR

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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