

# Protocol

## Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

(20118)

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### **Preauthorization is not 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.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With suspected obstructive sleep apnea	Interventions of interest are: • Home sleep testing with at least four recording channels	Comparators of interest are: • Polysomnography	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: • Mandibular advancement devices	Comparators of interest are: • Continuous positive airway pressure	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With suspected obstructive sleep apnea	Interventions of interest are: • Limited channel home sleep testing	Comparators of interest are: • In-laboratory polysomnography	Relevant outcomes include: • Test accuracy • Symptoms • Functional outcomes • Resource utilization
Individuals: • With obstructive sleep apnea	Interventions of interest are: • Novel obstructive sleep apnea treatments (e.g., expiratory positive airway pressure, oral pressure therapy)	Comparators of interest are: • Continuous positive airway pressure therapy • Home sleep testing with at least four recording channels	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 monitoring with type 3 monitors 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

For individuals who have suspected OSA who receive home sleep testing with at least four recording channels, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. RCTs have reported that home sleep testing with type 3 monitors (those with four or more recording channels) is noninferior to testing in the sleep lab for adults with a high pre-test 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 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 OSA who receive positive airway pressure or mandibular advancement devices, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. 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 auto-adjusting positive airway pressure (APAP) to evaluate efficacy and adjust pressure. APAP or bilevel positive airway pressure 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 suspected OSA who receive limited channel home sleep 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 heart rate, respiratory effort, airflow, and oxygen saturation lacks support in the literature. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have OSA who receive novel OSA treatments (e.g., expiratory positive airway pressure [EPAP], oral pressure therapy), the evidence includes one RCT and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence on EPAP devices in patients with OSA has been reported in prospective case series, one industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the Apnea/Hypopnea Index with minor impact on oxygenation and Epworth Sleepiness Scale score. One comparative trial with historical controls used 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. No evidence was identified on use of the oral therapy device. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Policy

#### *Diagnosis*

A single unattended (unsupervised) home sleep study with a minimum of four recording channels (including oxygen saturation, respiratory movement, airflow, and electrocardiogram [EKG] or heart rate) may be considered **medically necessary** in adults who are at high risk for obstructive sleep apnea (OSA) (The Policy Guidelines

define high pretest probability) and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including the following:

- central sleep apnea
- heart failure
- chronic pulmonary disease
- obesity hypoventilation syndrome
- neuromuscular disorders with sleep-related symptoms
- injurious or potentially injurious parasomnias or
- narcolepsy.

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

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

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

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 five events per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

Repeated unattended (unsupervised) home sleep studies with a minimum of four recording channels (including oxygen saturation, respiratory movement, airflow, and EKG or heart rate) 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 re-evaluate 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.

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 (i.e., less than 18 years of age); OR
2. When patients do not meet criteria for an unattended home sleep study as described above; OR
3. A previous home study failed to establish the diagnosis of OSA in a patient with a high pretest probability of OSA; OR
4. A previous home study was technically inadequate; OR
5. Failure of resolution of symptoms or recurrence of symptoms during treatment; OR
6. To reevaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued; OR

7. When testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy, OR
8. Presence of a comorbidity that might alter ventilation or decrease the accuracy of a home sleep study, including, but not limited to heart failure, neuromuscular disease, chronic pulmonary disease, or obesity hypoventilation syndrome.

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

1. To initiate and titrate CPAP in adults who have:

- An AHI of at least 15 events per hour, OR
- An AHI of at least five events per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

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

2. To initiate and titrate CPAP in children:

- In pediatric patients, an AHI greater than 1.5 events per hour is considered abnormal, and an AHI of 10 or more may be considered severe.

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

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

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

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

Remote monitoring is considered **not medically necessary**.

#### *Medical Management*

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

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

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

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

**Note:** CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in

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

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

### Policy Guidelines

#### *Risk Factors for Obstructive Sleep Apnea*

Although not an exclusive list, patients with all four of the following symptoms are considered to be at high risk for OSA:

- habitual snoring;
- observed apneas;
- excessive daytime sleepiness;
- a body mass index 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, or craniofacial or upper airway soft tissue abnormalities or unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; however, at present, risk assessment is based on clinical judgment.

The STOP-BANG questionnaire, a method developed for non-sleep specialists, assesses the signs and symptoms of OSA (**S**nore, **T**ired, **O**bserved apnea, blood **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 per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment, but is not adequate for the diagnosis of OSA. Therefore, a follow-up PSG or home sleep study would still be required to confirm or exclude a diagnosis of OSA.

#### *OSA in Children*

The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a body mass index greater than the 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 score of 10 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 study is the most accurate screening method. Some experts recommend a symptom based screening instrument, followed by PSG in patients who exceed a certain threshold, as an alternative to performing PSG in all patients. It should be noted that there is a high prevalence of obesity hypoventilation syndrome in patients who are candidates for bariatric surgery. Therefore, obesity hypoventilation syndrome should be ruled out prior to home sleep testing in this population.

### *Multiple Sleep Latency Test*

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

### *Specialist Training*

Medical professionals who interpret a polysomnogram or home sleep study should be trained in sleep medicine and should review the raw data from PSG and home sleep studies to detect artifacts and data loss. In addition, the treatment of patients diagnosed with OSA should be initiated and monitored by a physician (MD, DO). It is important to monitor symptoms and adherence to positive airway pressure (PAP) treatment (e.g., review of symptoms and device utilization between 30 and 90 days).

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.

### *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 of 20 to 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 pressure 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*

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 bioparameters, 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 con-

ducted 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 allow 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 with training 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 practi-



tioner 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.

#### *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

### *Description of Disease*

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 a 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.

A hallmark sign 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. Upper airway resistance syndrome is a variant of OSA characterized by a partial collapse of the airway, resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha electroencephalographic (EEG) arousals (“respiratory event-related arousals” [RERAs]). The sleep fragmentation associated 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 accidents 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. 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 accidents 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 diagnostic test for sleep disorders is a polysomnogram performed in a sleep laboratory.<sup>2</sup> A standard polysomnogram includes EEG, submental electromyogram (EMG), and electrooculogram (to detect rapid eye movement [REM] sleep) for sleep staging. Polysomnography (PSG) 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 CPAP in the second part of the night, commonly known as a “split-night” study. If successful, this strategy eliminates the need for an additional PSG for CPAP titration. Auto-adjusting positive airway pressure (APAP) may also be used to determine the most effective pressure.

Typically, the evaluation of OSA includes sleep staging to assess arousals from sleep and determination of the frequency of apneas and hypopneas. In adults, apnea is defined as a drop in the peak signal excursion (airflow) by 90% or more of pre-event baseline for at least 10 seconds.<sup>3</sup> Hypopnea in adults is scored when the peak signal excursions drop by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 3% arterial oxygen desaturation or an arousal. The Apnea/Hypopnea Index (AHI) and the Respiratory Disturbance Index (RDI) are two instruments that report on respiratory events during sleep. The AHI is defined as the total number of events per hour of sleep. RDI may be defined as the number of apneas, hypopneas, and RERAs

per hour of sleep. When sleep onset and offset are unknown (e.g., in home sleep studies), the RDI may be calculated based on the number of apneas and hypopneas per hour of recording time. A diagnosis of OSA is accepted when an adult has an AHI greater than five events per hour and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI of 15 or more events per hour is typically considered moderate OSA, while an AHI greater than 30 is considered severe OSA.

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. An apnea is scored when peak signal excursions (airflow) drop by at least 90% of pre-event baseline and the event meets duration and respiratory effort criteria for an obstructive, mixed, or central apnea.<sup>3</sup> A hypopnea is scored in children when the peak signal excursions drop is at least 30% of pre-event baseline for at least the duration of two breaths in association with either a 3% or greater oxygen desaturation or an arousal. 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. Although there is poor correlation between AHI and OSA symptoms, an increase in mortality is associated with an AHI of 15 or more events per hour in adults. Mortality has not been shown to be increased in adult patients with an AHI between five (considered normal) and 15 events per hour.

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

#### *Medical Management*

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 [BiPAP], or APAP) during sleep.

CPAP involves the administration of air, usually through the nose, by an external device at a fixed pressure to maintain the patency of the upper airway. BiPAP is similar to CPAP, but these devices are capable of generating two adjustable pressure levels. APAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been hypothesized that both BiPAP and APAP are more comfortable for the patient and thus might improve patient compliance or acceptance.

Oral appliances can be broadly categorized as mandibular advancing or positioning devices or tongue-retaining devices. Oral appliances can either be “off the shelf” or customized for the patient by a dental laboratory or similar provider.

Other devices being marketed for the treatment of OSA are 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 (OPT) to treat OSA. OPT provides light negative pressure to the oral cavity by using a flexible mouthpiece connected to a bedside console that delivers negative pressure. This device is proposed to increase the size of the retropalatal airway by pulling the soft palate forward and stabilizing the base of the tongue.

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 U.S. Food and Drug Administration (FDA) through the 510(k) process for treatment of snoring and mild-to-moderate sleep apnea, including the Narval™

CC, Lamberg Sleep Well Smartrusion, 1<sup>st</sup> 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 continuous positive airway pressure devices have received clearance through the 510(k) process since 1977. Bilevel positive airway pressure devices were first cleared for marketing by FDA in 1996. FDA product codes: BZD, MNT.

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

### Related Protocols

Actigraphy

Surgical Treatment of Snoring and Obstructive Sleep Apnea

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