
***Current Policy Effective Date: 7/1/21**
(See policy history boxes for previous effective dates)

Title: Sleep Disorders- Diagnosis and Medical Management

Description/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 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.

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 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 collisions involving motorized vehicles, ie, cars, trucks, or heavy equipment, while OSA in children may result in neurocognitive impairment and behavioral problems.

OSA can also affect the cardiovascular and pulmonary systems.[1] 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, and 20% have at least mild OSA and that the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease.[1]

Diagnosis

The criterion standard diagnostic test for sleep disorders is a polysomnogram performed in a sleep laboratory.[2] 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 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 an additional PSG for CPAP titration.

Table 1. Definitions of Terms and Scoring Criteria for OSA

Terms	Definition
Respiratory event	
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 2 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 at least 4% 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
Respiratory event reporting	
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	In adults: AHI or RDI of 5 to <15. In children: AHI ≥1.0 to <5
Moderate OSA	AHI or RDI of 15 to < 30; Children: AHI of ≥ 5 to <10
Severe OSA	Adults: AHI or RDI ≥30; Children: AHI of ≥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.
Positive airway pressure	
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 PSG 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 the use of various types of positive airway pressure (ie, 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 (ie, adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in the medical policy “Obstructive Sleep Apnea and Snoring, Surgical Management”.

Positional Obstructive Sleep Apnea and Therapy

Body position during sleep influences the frequency of apneas and hypopneas in 50-60% of those with OSA. In these cases, AHI is increased when in the person is in the supine position, and the AHI decreases in the lateral (side-lying) position.[3] There are many devices that propose “positional therapy” or “sleep positional training” for OSA. These devices may include home-made or retail items such as a vest with a pouch on the back to hold tennis balls, or a t-shirt with a center back pocket, also to house a tennis ball. These devices discourage supine sleeping. The U.S. Food and Drug Administration approved the NightBalance Lunoa SPT, a device which straps to the chest and emits a vibration to encourage movement from a supine position to a side-lying position.

Surgical management of OSA (ie, adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in the policy titled “Obstructive Sleep Apnea and Snoring – Surgical Treatment”.

Regulatory Status:

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

In 2014, the mRNA Appliance® (BioModeling Solutions, Beaverton, OH) was cleared for marketing by 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 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 FDA through the 510(k) process for the treatment of OSA. The Winx™ system/oral pressure therapy 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

In June 2018, NightBalance Lunoa SPT (Philips; Andover, MA) was given 510(k) premarket notification. Lunoa is used for the treatment of adult patients with positional obstructive sleep apnea with a non-supine apnea-hypopnea index <20. It records position and movement so that positional changes in sleep quality can be assessed.

Medical Policy Statement

Diagnosis

Polysomnography (PSG) is an attended (supervised) sleep study (sleep apnea test) performed in a hospital or freestanding sleep laboratory. The safety and effectiveness of PSG, including a split-night PSG, have been established. It may be considered a useful diagnostic option when indicated.

The safety and effectiveness of an unattended sleep study/sleep apnea test with a minimum of 3 recording channels (using, at a minimum, the following sensors: nasal pressure with chest and abdominal respiratory inductance plethysmography and oximetry; OR using Peripheral Arterial Tone [PAT] with oximetry and actigraphy) in a home setting (home sleep study/home sleep apnea test) have been established. It may be considered a useful diagnostic option when indicated.

The safety and effectiveness of multiple sleep latency testing (MSLT) have been established. It may be a useful tool in diagnosing narcolepsy.

Noninvasive pulse oximetry as a sole test (as an **alternative** to polysomnography or as a cardiorespiratory study for diagnosing sleep related breathing disorders) is considered experimental/investigational. Its effectiveness has not been established.

Medical Management

The safety and effectiveness of oral appliances to reduce upper airway collapsibility in the treatment of OSA have been established. An oral appliance may be considered a useful therapeutic option when indicated.

Palate and mandible expansion devices are considered experimental/investigational for the treatment of OSA. There is insufficient evidence in the current medical literature to support their efficacy and use in clinical practice.

Nasal Expiratory Positive Airway Pressure (nasal EPAP) for the treatment of OSA is considered experimental/investigational. There is insufficient evidence in the current medical literature to support its efficacy and use in clinical practice.

Oral pressure therapy for the treatment of OSA is considered experimental/investigational. There is insufficient medical literature found to support its efficacy.

Positional therapy devices, such as the NightBalance Lunoa SPT system, are considered experimental/investigational. They have not been proven to be more effective than standard care.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Diagnosis

UNATTENDED (UNSUPERVISED) HOME SLEEP STUDY, with minimum of 3 recording channels (using, at a minimum, the following sensors: nasal pressure with chest and abdominal respiratory inductance plethysmography and oximetry; OR using Peripheral Arterial Tone [PAT] with oximetry and actigraphy)

Inclusions:

- Adult patients 18 years of age or older with high pretest probability for moderate to severe OSA
  - Observed apneas during sleep; **OR**
  - A combination of **at least two (2)** of the following:
    - Excessive daytime sleepiness evidenced by an Epworth sleepiness >10, inappropriate daytime napping (eg, during driving, conversation or eating), or sleepiness that interferes with daily activities and is not explained by other conditions;
    - Habitual snoring or gasping/choking episodes associated with awakenings;

    - Treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications);
    - Obesity, defined as a body mass index (BMI) $\geq$ 35 kg/m^2 or neck circumference defined as >17 inches in men or >16 inches in women
    - Craniofacial or upper airway soft tissue abnormalities
    - Unexplained nocturia
- No exclusions/contraindications to a home sleep study

Exclusions/Contraindications:
- Younger than 18 years of age
- Morbid obesity, defined as a body mass index (BMI) $\geq$40 kg/m^2 or the patient is 100 pounds over the ideal body weight for their height
- Obesity hypoventilation syndrome
- Narcolepsy
- Periodic limb disorder during sleep
- Central sleep disorder
- Parasomnias
- Nocturnal seizures
- REM behavior disorder
- Moderate or severe congestive heart failure – New York Heart Association (NYHA) class III or IV
- Congestive heart failure with a history of ventricular fibrillation or sustained ventricular tachycardia in a patient who does not have an implanted defibrillator
- Moderate or severe chronic pulmonary disease – forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) less than or equal to 0.7 and FEV1 less than 80% of predicted
- Documented neuromuscular disease (eg, Parkinson's, myotonic dystrophy, ALS)
- History of stroke, severe insomnia or chronic opioid use
- Impairment that results in inability to apply the home sleep testing equipment
- Oxygen dependence

REPEAT UNATTENDED (UNSUPERVISED) HOME SLEEP STUDY, with a minimum of 3 recording channels using, at a minimum, the following sensors: nasal pressure with chest and abdominal respiratory inductance plethysmography and oximetry; OR using Peripheral Arterial Tone [PAT] with oximetry and actigraphy)

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

ATTENDED (SUPERVISED) SLEEP STUDY PERFORMED IN A SLEEP LAB
Note: Check our pre-authorization program for in-lab sleep testing. All procedures/codes may not be covered by all contracts or certificates.

Adults (18 years of age or older):

Inclusions:

- Adult patients 18 years of age or older with a moderate to high pretest probability for OSA
  - Observed apneas during sleep; **OR**
  - A combination of **at least two (2)** of the following:
    - Excessive daytime sleepiness evidenced by an Epworth sleepiness >10, inappropriate daytime napping (eg, during driving, conversation or eating), or sleepiness that interferes with daily activities and is not explained by other conditions;
    - Habitual snoring or gasping/choking episodes associated with awakenings;
    - Treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications);
    - Obesity, defined as a body mass index (BMI) $\geq$35 kg/m^2 or neck circumference > 17 inches in men or >16 inches in women
    - Craniofacial or upper airway soft tissue abnormalities
    - Unexplained nocturia
- When unattended (unsupervised) home sleep study is contraindicated (see exclusions/contraindications to unattended home sleep study above)
- When the initial unattended (unsupervised) study was negative, inadequate, equivocal or non-diagnostic and clinical suspicion for OSA remains

<u>Children</u> (younger than 18 years of age)

Inclusions:

- Pediatric patients younger than 18 years of age with a moderate to high probability of OSA
  - Habitual snoring in association with one or more of criteria below:
    - Restless or disturbed sleep
    - Behavioral disturbance or learning disorders including deterioration in academic performance, attention deficit disorder, hyperactivity
    - Frequent awakenings
    - Enuresis (bedwetting)
    - Growth retardation or failure to thrive; **OR**
  - Excessive daytime somnolence or altered mental status not explained by other conditions; **OR**
  - Polycythemia not explained by other conditions; **OR**
  - Cor pulmonale not explained by other conditions; **OR**
  - Witnessed apnea with duration greater than two (2) respiratory cycles; **OR**
  - Labored breathing during sleep; **OR**
  - Hypertrophy of the tonsils or adenoids in patients at significant surgical risk such that the exclusion of OSA would allow avoidance of surgery; **OR**
  - Suspected congenital central alveolar hypoventilation syndrome or sleep-related hypoventilation due to neuromuscular disease or chest wall deformities; **OR**
  - Clinical evidence of a sleep-related breathing disorder in infants who have experienced an apparent life-threatening event; **OR**
  - For exclusion of OSA in a patient who has undergone adenotonsillectomy for suspected OSA more than eight (8) weeks previously; **OR**
  - The initial study was inadequate, equivocal or non-diagnostic and the child's parents or caregiver report that the breathing patterns observed at home were different from those during testing.

<u>REPEATED (ATTENDED) SLEEP STUDY PERFORMED IN A SLEEP LAB</u>:

Inclusions:

- Equipment failure or less than six (6) hours of recording.
- Initial PSG is negative and a clinical suspicion of OSA remains
- To initiate and titrate CPAP in adult patients who have:
  - An AHI or RDI of at least 15 events per hour, OR
  - An AHI or RDI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension.

  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.
- To initiate and titrate CPAP in children:
  - In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 10 or more may be considered severe.
- To reevaluate the diagnosis of OSA and need for continued CPAP (eg, if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued.
  - **Note:** This statement does not imply that supervised studies are needed routinely following unattended studies. This statement means a re-evaluation based on a substantial change in symptoms or in the clinical situation.
- To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices

MUTLIPLE SLEEP LATENCY TESTING (MSLT)

MSLT is considered experimental/investigational to diagnose obstructive sleep apnea (OSA) except to exclude or confirm narcolepsy in the diagnostic workup of OSA syndrome.

The effectiveness of noninvasive pulse oximetry as a sole test (as an **alternative** to polysomnography or as a cardiorespiratory study for diagnosing sleep related breathing disorders) is considered experimental/investigational. Its effectiveness has not been established.

MEDICAL MANAGEMENT

PAP THERAPIES ie, continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP), bilevel positive airway pressure (BiPAP) and variable positive airway pressure (VPAP) may be considered medically necessary for the management of OSA, central sleep apnea or mixed apnea. These devices for treatment are addressed in policy titled "Positive Pressure Airway Devices".

ORAL APPLIANCES for OSA (eg, tongue-retaining devices or mandibular orthopedic positioning devices), may be considered established in adult patients with clinically significant OSA. (Verify coverage of intraoral appliances under the DME benefit.)

Definition of an Oral Appliance for OSA[42]

- A custom-fabricated appliance, using digital or physical impressions and models of an individual patient's oral structures and physical needs
- NOT a prefabricated item that is modified. Prefabricated components may be included in the final appliance.
- Includes all appliances, including titration appliances
- Made of biocompatible materials

- Engages the maxillary and mandibular arches
- Includes a mechanism that advances the mandible in increments of 1 mm or less with a protrusive adjustment range of at least 5 mm. This mechanism may or may not include fixed mechanical hinges or metallic materials.
- Reversal of the advancement is possible
- The protrusive setting must be verifiable[42]

  An appropriate oral appliance will allow for optimal protrusion of the mandible (eg, less than 5 mm) to produce the desired relative opening of the airway, without contributing to an increased risk of temporal mandibular joint dysfunction.

INCLUSIONS:
- OSA, as defined by:
  - an AHI, RDI or REI of at least 15 events per hour, OR
  - an AHI, RDI or REI of at least 5 events per hour in a patient with excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, or history of stroke AND
- A trial of CPAP has failed, is not tolerated by the patient, or is contraindicated; AND
- The device is prescribed by the treating physician; AND
- The device is custom-fitted by a dentist (preferably a dentist with certification/additional training in dental sleep medicine); AND
- There is a dental evaluation that documents:
  - absence of both temporomandibular dysfunction and periodontal disease; AND
- Impressions, models, fabrication, materials, insertion/fitting, training, subsequent adjustments/modifications of the appliance, repairs and ancillary appliances are included with the OSA appliance and are not separately billable for the first 90 days after provision of the oral appliance.

  Replacement of an oral appliance may be considered at the end of the 5-year reasonable useful lifetime (RUL), or prior, if there is a change in the patient's condition.

EXCLUSIONS:
- Prefabricated (not custom-fit) devices (eg, sport mouth guards, mouth guards which can be purchased in a retail store or pharmacy)
- Screening tests (eg, questionnaire, pulse oximetry, rhinometry, and laryngometry, etc.) performed by a dentist

Palate and mandible expansion devices are considered **experimental/investigational**.
Nasal Expiratory Positive Airway Pressure is considered **experimental/investigational**.
Oral pressure therapy is considered **experimental/investigational**.

Positional therapy devices, such as the NightBalance Lunoa SPT system, are considered **experimental/investigational**. They have not been proven to be more effective than standard care.

POLICY GUIDELINES

Polysomnography or home sleep apnea testing is ordered by a physician or qualified healthcare provider who has evaluated the patient and is managing the medical care of the patient, ie, either a primary care physician or a specialist. Following the review of the sleep

study results, recommendations for the most appropriate medical treatment may be made by the treating physician/QHP, or may be a collaborative effort between the treating physician/QHP and the board-certified sleep medicine physician who interprets the results of the testing.

Facility/Provider Requirements

If an attended sleep study is performed in a non-hospital-based sleep laboratory, the laboratory must be accredited by the American Academy of Sleep Medicine (AASM).

An attended sleep study in a hospital-based sleep testing center must be accredited by AASM or an accreditation organization accepted under the Participating Hospital Agreement.

In order to perform and receive reimbursement for in-center and out-of-center sleep testing, a physician must be board-certified in sleep medicine by the American Board of Medical Specialties or the American Board of Sleep Medicine. Any MD or DO may order a sleep test; however, it must be performed and interpreted by a physician who is board-certified in sleep medicine.

The technician performing the sleep testing must have one of the following certifications:

- American Board of Sleep Medicine, Registered Sleep Technologist, OR
- Board of Registered Polysomnographic Technologists, Registered Polysomnographic Technologist, OR
- National Board for Respiratory Care (any of the following):
  - Certified Pulmonary Function Technologist
  - Registered Pulmonary Function Technologist
  - Certified Respiratory Therapist
  - Registered Respiratory Therapist

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

Risk Factors for OSA

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

- habitual snoring;
- observed apneas;
- excessive daytime sleepiness;
- a body mass index (BMI) greater than 35 kg/m^2.

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

The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (Snore, Tired, Observed apnea, blood Pressure, BMI, Age, Neck, Gender) and has been shown to have 97% sensitivity and 96% negative predictive value

(specificity, 33%) for the identification of patients with severe OSA (Apnea/Hypopnea Index [AHI] score >30 events 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 polysomnography (PSG) or home sleep study/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 body mass index greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI or RDI greater than 1.5 events per hour is considered abnormal (an AHI or RDI of $\geq$10 events per hour may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. Continuous positive airway pressure (CPAP) is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

Bariatric Surgery Patients

Screening for OSA should be performed routinely in patients scheduled for bariatric surgery, due to the high prevalence of OSA in this population. The optimal screening approach is not certain. An in-laboratory PSG or home sleep study/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 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 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, OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.

Split-Night Studies

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

a. An AHI of at least 40 is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI of 20 to 40 events per hour, based on clinical judgment (eg, if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP-level requirements, based on split-night studies, may be less accurate than in full-night calibrations.
b. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).
c. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM 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.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

95782	95783	95800	95805	95806
95807	95808	95810	95811	E0486
G0398	G0399			

Other codes (investigational, not medically necessary, etc.):

95801*	A7047	E0485	E1399	G0400*

*May be covered for Medicare if criteria is met

Note: Code(s) G0398-G0399 may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias

and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

SUSPECTED OBSTRUCTIVE SLEEP APNEA

Clinical Context and Test Purpose

The purpose of home sleep apnea tests in patients with suspected obstructive sleep apnea (OSA) is to diagnosis the condition and to inform a decision on appropriate treatment.

The question addressed in this evidence review is: Do home sleep apnea tests improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients

The relevant populations of interest is patients with suspected OSA.

Interventions

The test being considered is home sleep apnea testing. Tests reviewed are multichannel home sleep testing and limited channel sleep testing (auto-adjusting positive airway pressure [APAP], Apnea Risk Evaluation System).

Comparators

The established test for OSA is in-laboratory polysomnography (PSG). Laboratory PSG is a more complex procedure than home testing and more limited in its availability.

Outcomes

The general outcomes of interest are the number of apneas or hypopneas during sleep, measured by the Apnea/Hypopnea Index (AHI), and subjective symptoms of sleepiness, typically measured with the Epworth Sleepiness Scale (ESS) or the Functional Outcomes of Sleep Questionnaire (FOSQ) (see Table 2).

Table 2. Health Outcome Measures Relevant to OSA

Outcome	Measure	Description	Clinically Meaningful Difference (If Known)
Change in AHI	AHI	Mean change in AHI from baseline to posttreatment	Change from severe-to-moderate or mild OSA
AHI success	Percentage of patients achieving success	Studies may use different definitions of success, but the most common for AHI success is the Sher criteria	Sher criteria include a decrease in AHI of ≥50% and an AHI <20 events per hour. Alternative measures of success may be AHI <15, <10, or <5 events per hour
ODI	Oxygen levels in blood during sleep	The number of times per hour of sleep that the blood oxygen level drops by ≥4 percentage points	More than 5 events per hour
ESS	Scale ranges from 0 to 24	The ESS is a short self-administered questionnaire that asks patients how likely they are to fall asleep in 8 different situations (eg, watching TV,	An ESS of ≥10 is considered excessively sleepy

		sitting quietly in a car, or sitting and talking to someone)	
FOSQ	30 questions	Disease-specific quality of life questionnaire that evaluates functional status related to excessive sleepiness	A score of ≥18 is the threshold for normal sleep-related functioning, and a change of ≥2 points is considered a clinically meaningful improvement

AHI: Apnea/Hypopnea Index; ESS: Epworth Sleepiness Score; FOSQ: Functional Outcomes of Sleep Questionnaire; ODI: Oxygen Desaturation Index; OSA: obstructive sleep apnea.

Beneficial outcomes of a true positive are effective treatment resulting in a decrease in respiratory events during sleep and a reduction in subject sleepiness.

Harmful outcomes of a false-positive test include unnecessary treatment. Harmful outcomes of a false negative test include not receiving the correct treatment.

REVIEW OF EVIDENCE

Multichannel Home Sleep Testing

Balk et al (2011) conducted a comparative effectiveness review for the Agency for Healthcare Research and Quality (AHRQ) on the diagnosis and treatment of OSA in adults. Reviewers found strong evidence that an AHI greater than 30 events per hour is an independent predictor of all-cause mortality, with low or insufficient evidence for an association between AHI and other clinical outcomes. Reviewers found moderate evidence that type 3 and type 4 monitors may have the ability to accurately predict an AHI suggestive of OSA and that type 3 monitors perform better than type 4 monitors at AHI cutoffs of 5, 10, and 15 events per hour.

Home sleep testing with three recording channels that include respiratory effort, airflow, and oxygen saturation, but not heart rate, are considered by some, including the Centers for Medicare & Medicaid, to be sufficient for home sleep studies. Corral et al (2017) reported a multicenter noninferiority trial of home sleep testing using a 3-channel monitor compared with in-laboratory PSG in 430 patients.[5] Included in the study were patients referred to tertiary hospitals in Spain for suspected OSA, who had snoring or sleep apneas observed by a partner, ESS score of ten or greater, and absence of clinical suspicion of any other sleep pathology. Both groups of patients who were diagnosed with OSA received continuous positive airway pressure (CPAP) titration with a single APAP session at home. The median baseline ESS score was 13 in both groups. CPAP was indicated in 68% of patients in the PSG arm compared with 53% in the home sleep testing group, with the difference attributed to the underestimation of AHI in home sleep studies. All patients, including those treated with CPAP and those who were not, were assessed at six-month follow-up. ESS score improved by -4.2 (95% confidence interval [CI], -4.8 to -3.6) in the home sleep testing group and by -4.9 (95% CI, -5.4 to -4.3) in the PSG group. With a noninferiority margin of two points on the ESS, home sleep testing was noninferior to in-laboratory PSG.

Section Summary: Multichannel Home Sleep Testing

Based on this evidence and society guidelines, portable monitoring with a minimum of four recording channels (including oxygen saturation, respiratory movements, airflow, and electrocardiogram or heart rate), or with a device that measures peripheral arterial tone, actigraphy, and oxygen saturation, for diagnosis of OSA in adults who are at high risk for OSA

improves outcomes, when clinical evaluation and follow-up are conducted by a medical professional experienced in the diagnosis and treatment of sleep disorders.

Limited Channel Home Sleep Testing

Use of Auto-Adjusting Positive Airway Pressure for Diagnosis and Treatment Supervised by a Sleep Specialist

Mulgrew et al (2007) published a randomized validation study of the diagnosis and management of OSA with a single-channel monitor followed by auto-adjusting positive airway pressure (APAP).[6] They developed a diagnostic algorithm that had a 94% positive predictive value (PPV) for moderate-to-severe OSA assessed by PSG. Patients who passed the screening (n=68) were randomized to attended in-laboratory PSG with CPAP titration or to home monitoring with a portable APAP unit. No difference was observed between lab-PSG and home-managed patients for any of the outcome measures. Senn et al (2006) assessed whether an empiric approach, using a two-week trial of APAP, could effectively diagnose OSA.[7] Patients (n=76) were included in the study if they had been referred by primary care physicians for evaluation of suspected OSA, were habitual snorers, complained of daytime sleepiness, and had an ESS score of 8 or greater (mean, 13.6). At the end of the two-week trial, patients were asked to rate the perceived effect of treatment and to indicate whether they had used CPAP for more than two hours per night and were willing to continue treatment. Patients without a clear benefit of CPAP received further evaluation, including clinical assessment and PSG. Compared with PSG, patient responses showed a sensitivity of 80%, a specificity of 97%, a positive predictive value of 97%, and a negative predictive value of 78%.

Berry et al (2008) randomized 106 patients referred for a sleep study for suspected OSA at a local Veterans Administration center to portable monitoring followed by APAP or to PSG for diagnosis and treatment.[8] Patients were screened with a detailed sleep and medical history questionnaire, and patients on α-blockers or not in sinus rhythm were excluded due to the type of portable monitoring device used (Watch-PAT™ 100). Of the 53 patients randomized to PSG, 6 (11%) did not have PSG-defined OSA; in the portable monitoring arm, 4 (8%) of 53 patients were found not to have OSA. Treatment outcomes were similar in both groups, with a 7-point improvement in ESS score, 3-point improvement in the Functional Outcomes of Sleep Questionnaire score, and a machine estimate of residual AHI of 3.5 events per hour in the portable monitoring APAP group and 5.3 in the PSG group.

Apnea Risk Evaluation System

Ayappa et al (2008) reported on a validation study of a small apnea monitor that is self-applied to the forehead.[9] The device measures blood oxygen saturation and pulse rate, airflow, snoring levels, head movement, and head position. The study enrolled 80 individuals with a high likelihood of OSA and 22 with a low risk of OSA; results of simultaneous Apnea Risk Evaluation System (ARES) recording and PSG were available for 92 individuals. When healthy subjects were excluded from the analysis, sensitivity (91%) and specificity (92%) were relatively high for an AHI of 15 or more events per hour but dropped considerably with an AHI between 5 and 15 (sensitivity, 97%; specificity, 78%). Five percent of the subjects could not tolerate the device and were not included in the analysis.

SleepImage System

The SleepImage System is cloud-based software as a medical device that generates AHI from data recorded with a single photoplethysmogram sensor. The SleepImage algorithms calculate heart rate variability, respiration, and oxygen saturation with cardiopulmonary coupling

analysis. Hilmisson et al (2020) compared results calculated by the SleepImage System with manually scored PSG in 805 children ages 5 to 9.9 yrs of age who participated in the Childhood Adenotonsillectomy Trial (CHAT).[10] The CHAT study included 1244 habitually snoring children who were referred for PSG. A total of 805 children had successfully collected data from the sensor. Concordance between the SleepImage-derived AHI and PSG-derived AHI is shown in Table 3. Kappa was 0.81, 0.89, and 0.91 for mild, moderate, and severe sleep apnea, respectively. A proposed benefit is that this would be easier for children compared to a test requiring multiple sensors and improve access. Further study in a wider population is needed to evaluate whether this system might be a suitable method for evaluating sleep parameters in the home.

Table 3. Clinical Validity of the SleepImage System

Study	Initial N	Final N	Excluded Samples	Prevalence of Condition	Clinical Validity: Agreement (95% CI)		
					Mild Sleep Apnea AHI > 1.0	Moderate Sleep Apnea AHI > 5.0	High Risk AHI > 10.0
Hilmission et al (2020)[9],	1244	805	439	64%	0.914 (0.895 to 0.934)	0.967 (0.954 to 0.979)	0.986 (0.978 to 0.994)

CI: confidence interval

Subsection Summary: Limited Channel Home Sleep Testing
The evidence for limited channel home sleep testing (includes type four monitors) in patients who have OSA consists of studies on diagnostic accuracy. A number of questions remain about the ability of these home sleep apnea tests to detect clinically significant OSA without sensors for respiratory effort, airflow, and oxygen saturation (or alternatively, peripheral arterial tone, actigraphy, and oxygen saturation).

DIAGNOSED OBSTRUCTIVE SLEEP APNEA

Clinical Context and Therapy Purpose
The purpose of medical management in patients who have OSA is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does management with PAP, oral appliances, or novel OSA treatments improve the net health outcome?

The following PICO was used to select literature to inform this review.

Patients
The relevant population of interest is patients with OSA.

Interventions

Positive airway pressure therapies for the treatment of OSA are addressed in the policy titled “Positive Pressure Airway Devices”.

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.

The Daytime-Nighttime Appliance (DNA Appliance) and the mandibular Repositioning Nighttime Appliance (mRNA Appliance) are customized palate and mandible expanding devices. In addition to the upper-jaw device that is common to both the DNA Appliance and the rRNA Appliance (worn both during the day and night), the mRNA Appliance moves the mandible forward and is worn during sleep. The DNA Appliance and mRNA Appliance systems use 3-dimensional axial springs, which are proposed to expand the upper and lower jaw and airway gradually to treat and eventually eliminate mild-to-moderate OSA.

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 to treat OSA. Oral pressure therapy 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.

Comparators

The following therapy is currently being used to make decisions about the treatment of OSA. The criterion standard treatment is CPAP or its variants. The major limitation of CPAP is poor patient compliance due to the need to wear a face or nasal mask.

Outcomes

The outcomes of interest are a decrease in AHI and Oxygen Desaturation Index on PSG and improvement in a measure of sleepiness such as the ESS or FOSQ (see Table 2), which are typically conducted within weeks or months.

REVIEW OF EVIDENCE

Oral Appliances

A systematic review of the evidence on the treatment of OSA with oral appliance therapy was performed by Ramar et al (2015), as part of an update of practice guidelines by American Academy of Sleep Medicine and the American Academy of Dental Sleep Medicine.[11] Meta-analysis showed that oral appliances reduced the AHI, arousal index, and Oxygen Desaturation Index, and increased oxygen saturation. However, oral appliances had no significant effect on sleep architecture or sleep efficiency. The meta-analysis found CPAP to be more effective than oral appliances in reducing the AHI, arousal index, and Oxygen Desaturation Index, and in improving oxygen desaturation, supporting the use of CPAP as a first-line therapy for treating OSA.

Johal et al (2017) reported on a randomized crossover trial of ready-made vs custom-made mandibular repositioning devices.[12] Twenty-five patients with mild-to-moderate OSA (mean AHI, 13.3 events per hour; range, 10.9-25 events per hour) were randomized to a 3-month trial of a ready-made or the custom-made device, with a 2-week washout between treatments. An overnight home sleep study was performed at baseline and on the last night of the 3-month trial period. Patients used the custom-made device for more nights per week (7 vs 3, p=0.004) and hours per night (5 vs 3, p=0.006) than the ready-made device. Treatment response (AHI <5 events per hour) was obtained in 64% of patients during use of the custom-made device phase compared with a 24% response rate using the ready-made device (p<0.001). Treatment failure (<50% reduction in SHA) was more frequent with the ready-made device (36%) than

with the custom device (4%), while an ESS score of at least 10 was more frequent during the ready-made phase (66%) than with the custom-made phase (33%). An improvement in the QOL score was observed only during the custom-made device phase.

In the AHRQ report (2011) on the diagnosis and treatment of OSA in adults, the strength of the evidence that mandibular advancement devices improve sleep apnea signs and symptoms was rated moderate.[4]

Subsection Summary: Oral Appliances
Custom oral appliances, which may include mandibular repositioning or tongue-retaining devices, are an accepted therapy for mild-to-moderate OSA. A 2015 meta-analysis found efficacy of oral appliances for measures of OSA, but they were less effective than CPAP. The strength of evidence for mandibular repositioning devices was rated as moderate by AHRQ.

Positional Therapy
Van Maanen et al (2013) reported on a study performed in The Netherlands of 36 patients with mild-to-moderate positional obstructive apnea who were presented with a novel device, the Sleep Position Trainer, for treatment.[13] Thirty-one patients completed the one-month trial. The authors concluded that the Sleep Position Trainer was highly successful, well-tolerated and improved sleep-related quality of life.

Eijsvogel et al (2015) reported on compliance of positional therapy in positional obstructive sleep apnea syndrome.[14] Twenty-nine patients were treated with the sleep position trainer (SPT) while 26 patients were treated with the tennis ball technique. At baseline and 1 month polysomnography, the ESS and the Quebec Sleep Questionnaire (QSQ) were taken. Daily compliance was objectively measured in both groups. Both therapies prevent supine sleep position to a median of 0%, resulting in a treatment success (AHI < 5) in 68.0% of the SPT and 42.9% of the TBT patients. The ESS at baseline was < 10 in both groups. Sleep quality parameters, such as wake after sleep onset and awakenings improved more in the SPT group. The authors concluded that in mild positional obstructive sleep apnea with normal EES, the new SPT device and the standard TBT are equally effective in reducing respiratory indices.

de Ruiter et al (2017)[15] reported on a study comparing the effectiveness of positional therapy (PT) with the sleep position trainer to oral appliance therapy in patients with mild-to-moderate positional obstructive sleep apnea. This was a multicenter, prospective, randomized, controlled trial. Patients with mild-to-moderate POSA (apnea-hypopnea index (AHI) ≥5 ≤ 30/hour sleep) were randomized for PT or oral appliance therapy. Polysomnography was repeated after 3 months. Efficacy, adherence, mean disease alleviation (MDA), quality of life, dropouts and adverse events were evaluated. A total of 177 patients were screened for the study; 99 underwent randomization and 81 completed the study. Intention-to-treat (ITT) analysis of median [IQR] AHI showed a reduction in the PT group from 13.0 [9.7-18.5] to 7.0 [3.8-12.8], $p < 0.001$ and in the OAT group from 11.7 [9.0-16.2] to 9.1 [4.9-11.7], $p < 0.001$. Mean adherence (≥4 h/night, ≥5 days/week) was 89.3 ± 22.4% for SPT versus 81.3 ± 30.0% in OAT patients, $p = 0.208$. The authors concluded that oral appliance therapy and positional therapy were equally effective in reducing the median AHI in patients with mild-to-moderate POSA.

Subsection Summary: Positional Therapy
For those whose body position during sleep influences the frequency of apneas and hypopneas, positional devices that discourage the supine position are effective. However, the

devices are not significantly more effective than a tennis ball on the back of a shirt, or oral appliance therapy.

NOVEL OSA TREATMENTS

Palate and Mandible Expansion

Singh et al (2016) reported on a series of 15 consecutive patients with severe sleep apnea who were treated with a DNA Appliance or mRNA Appliance.[16] All patients had failed to comply with CPAP. Pre- and post-treatment AHI was assessed in a home sleep apnea test without the oral appliance. AHI decreased from a mean 45.9 events per hour to 16.5 ($p<0.01$) after a mean 9.7 months of treatment. Singh et al (2016) and Cress (2017) reported on a series of 19 patients who had mild-to-moderate OSA who were treated with a DNA or mRNA Appliance.[17] Only patients who complied with oral appliance wear were included in the study. The mean AHI was reduced from 12.85 to 6.2 events per hour ($p<0.001$) with the appliance, while the Oxygen Saturation Index improved from 6.3% to 2.6% ($p<0.001$). Limitations of these studies included the use of a home sleep apnea test rather than the more accurate laboratory PSG, uncertain blinding of the physician evaluating the sleep study, the small number of patients studied, the lack of intention-to-treat analysis, and the lack of long-term follow-up.

PAP-NAP

Krakow et al (2008) reported on use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP.[18] Patients had been referred by psychiatrists or primary care physicians for unspecified insomnia conditions, insomnia due to a mental disorder, or hypnotic dependence. Nearly all patients had anxiety, fear, and/or resistance regarding PAP therapy or the diagnosis of OSA. Thirty-nine patients who would not complete a titration protocol (full-night or split-night) were offered a daytime procedure (PAP-NAP) prior to night-time titration. The PAP-NAP protocol had 5 components: pretest instructions to maximize chances for daytime napping; introduction of PAP therapy addressing barriers to use; type 3 monitoring hookup (10 channels without electroencephalography leads); PAP therapy during one to two hours in bed in which the patient had the opportunity to fall asleep with the mask in place; and post-test follow-up. Thirty-five of 39 nap-tested patients subsequently scheduled and completed an overnight titration or split-night study with full PSG. The effect of the PAP-NAP intervention on compliance was compared with historical controls (n=38) who had insomnia, mental health conditions, and OSA with resistance to CPAP who completed titration. A prescription for PAP therapy was filled by 85% of the PAPNAP group compared with 35% of controls. Regular use during a 30-day period was recorded by the PAP device in 67% of the intervention group and in 23% of controls. Adherence, defined as at least 5 days a week with an average of at least 4 hours a day, was 56% in the PAP-NAP group and 17% in controls.

Nasal Expiratory Positive Airway Pressure

Evidence on nasal expiratory positive airway pressure (EPAP) includes a moderately sized RCT and a systematic review on the Provent device.

Berry et al (2011) reported on an industry-sponsored multicenter, double-blind, randomized sham-controlled trial of EPAP.[19] Two hundred fifty patients with OSA and an AHI of 10 or more events per hour were randomized to nasal EPAP (n=127) or to a sham device (n=123) for 3 months. PSG was performed on 2 nights (device-on, device off, in a random order) at week 1 (92% follow-up) and after 3 months of treatment (78% follow-up). EPAP reduced median AHI from 13.8 to 5.0 events per hour (-52.7%) at week 1 and from 14.4 to 5.6 events per hour (-42.7%) at 3 months. This reduction in AHI in the treatment group was significantly greater (-

7.3% at week 1, -10.1% at 3 months) than in the sham group. Over 3 months, the decrease in ESS score was statistically greater in the EPAP group (from 9.9 to 7.2) than in the sham group (from 9.6 to 8.3), although the clinical significance of a 1-point difference in ESS score is unclear. Treatment success and oxygenation data were presented only for the 58% of per-protocol patients who had an AHI of 5 or more events per hour on the device-off PSG night. The oxygenation results (Oxygenation Desaturation Index and percent of total sleep time with oxygen saturation <90%) showed small but statistically significant decreases at 1 week and 3 months. Treatment success, defined as a 50% or greater reduction in the AHI or an AHI reduction to less than 10 events per hour (if device-off AHI was ≥10 events per hour), was greater in the EPAP group at 1 week (62% vs 27.2%) and at 3 months (50.7% vs 22.4%). Device-related adverse events were reported by 45% of patients in the EPAP group and by 34% of patients in the sham group, with 7% of patients in the EPAP group discontinuing due to adverse events. Overall, the validity of these results was limited by the high dropout rate, and the clinical significance of the results is uncertain.

Kryger et al (2011), in an open-label extension of the 2011 randomized study by Berry et al (2011), evaluated 12-month safety and durability of the treatment response in patients who had an initially favorable response to EPAP.[20] Included were 41 (32%) of the 127 patients in the EPAP arm of the study who used the device for an average of at least 4 hours per night on at least 5 nights a week during months 1 and 2 and had at least a 50% reduction in AHI, or reduction to less than 10 events per hour, compared to the device-off PSG. Of the 51 (40%) of 127 eligible patients, 41 enrolled in the extension study, and 34 (27%) of 127 were still using the EPAP device at the end of 12 months. Median AHI was reduced from 15.7 to 4.7 events per hour; the percentage of patients who met criteria for success was not reported. The arousal index was modestly decreased (from 23.9 to 19.0). After 12 months of treatment, the ESS score decreased from 11.1 to 6.0. The median percentage of reported nights used (entire night) was 89.3%. Device-related adverse events were reported by 42% of patients, most frequently difficulty exhaling, nasal discomfort, dry mouth, headache, and insomnia. This open-label extension study was limited by its inclusion only of responders and by the potential for a placebo effect on the ESS score. However, the data suggested that some patients might have responded to this device, and the patient compliance data might indicate a positive effect on daytime sleepiness that leads to continued use of the device in about 25% of patients. Additional controlled studies are needed to distinguish between these alternatives.

A systematic review by Riaz et al (2015) identified 18 studies (N=920 patients) that had data on pre- and post-nasal EPAP.[21] Study designs included 10 conference papers and 8 publications (case series, cohort studies, RCTs). For patients included in the meta-analysis (n=345 patients), AHI decreased from 27.32 to 12.78 events per hour ($p<0.001$). For 359 patients, ESS score modestly improved from 9.9 to 7.4 ($p<0.001$). Data from the Berry et al (2011) RCT (described above) were not included in this meta-analysis because mean data were not reported. Response to nasal EPAP was variable and inconsistent, and there were no clear characteristics (demographic factors, medical history, and/or physical exam finding) that predicted a favorable response.

Kureshi et al (2014) reported on a small (n=14) double-blind, pilot, crossover RCT of EPAP in children to evaluate efficacy and compliance with this new treatment.[22] PSG with EPAP or a placebo device showed a significant mean improvement in Obstructive Apnea Index with EPAP (0.6 versus 4.2, $p=0.01$), but responses varied (3 did not improve, 2 worsened). No other measures were statistically significant in this trial. For responders who used the devices at home for 30 days, adherence was 83% of nights. ESS scores improved from 11 to 7

(p=0.031) and Obstructive Sleep Apnea-18 questionnaire scores improved from 50 to 39 (p=0.028). Other outcome measures did not improve significantly.

Oral and OroNasal Pressure Therapy
Lai et al (2019) reported a study with 22 patients with OSA who were incomplete responders to an oral appliance (AHI > 5).[23] They were assessed with the oral appliance plus either an oral or an oronasal EPAP. Both the oral and oral/nasal devices were studied in the same night (split night PSG); the order of the EPAP devices was randomized. Power analysis indicated that 20 participants would be sufficient to detect an AHI difference of 7 between conditions. Five patients (23%) had at least a 50% reduction in total AHI with the oral EPAP compared to the oral appliance alone, while 10 patients (45%) had a 50% reduction in AHI with the combined oral and nasal EPAP valves. Neither of these was statistically significant. Only 2 patients (9%) achieved an AHI of less than 5 with the oral EPAP device compared to 9 (41%) with the combined oral and nasal valves. However, sleep efficiency was disrupted with the oronasal EPAP valves.

Subsection Summary: Novel OSA Treatments
The evidence on palate and mandible expansion devices includes a few small cohort studies. 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 several 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 AHI with a minor impact on oxygenation and ESS score. An oral EPAP device did not have significant benefit when added to an oral appliance.

One comparative trial with historical controls used a PAP-NAP study of patients with complex insomnia who were resistant to CPAP titration or use. This single study of PAP-NAP does not provide sufficient evidence to form conclusions on the efficacy of this approach in improving compliance with CPAP. The patient population was highly selected and the behavioral intervention may be dependent on the specific clinicians providing treatment. In addition, historical controls were used, and they were not well-matched to the study population. For these reasons, the internal validity and generalizability of the results are uncertain.

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 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 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 APAP to evaluate efficacy and adjust pressure. APA or bilevel PAA 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 (eg, palate expansion, nasal EPAP , oral pressure therapy), the evidence includes RCTs and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. 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

SUPPLEMENTAL INFORMATION

In response to requests, the Blue Cross Blue Shield Association received input from 7 physician specialty societies (8 reviewers) and 4 academic medical centers (6 reviewers) while their policy was under review in 2014. The input focused on routine screening of patients scheduled to undergo bariatric surgery. There was consensus that routine screening is considered medically necessary in this population due to the high prevalence of OSA in patients with a body mass index greater than 40, combined with the increased rate of perioperative complications in patients with OSA. Input was mixed on whether the use of portable home sleep testing was appropriate for patients scheduled for bariatric surgery. Concerns were raised about the high prevalence of obesity hypoventilation syndrome in this population, which is a contraindication to home sleep testing. Other reviewers considered home sleep testing to be appropriate in patients scheduled for bariatric surgery, with the caveat that obesity hypoventilation syndrome should be ruled out prior to home sleep testing.

2010 Input
In response to requests, the BCBSA received input from 1 physician specialty society and 6 academic medical centers (8 reviewers) for their 2010 policy update. The input focused on the

sensors required for unattended home sleep studies and on diagnosis and treatment of OSA in children. In general, the reviewers supported the requirement that home monitors measure 4 parameters, including respiratory effort, airflow, and oxygen saturation, and that their use be restricted to adults. Some exceptions were noted for specific situations. The update included recommendations from reviewers regarding indications that are specific to pediatric patients.

2009 Input

In response to requests, the BCBSA received input from 5 physician specialty societies (6 reviewers) and 3 academic medical centers while their policy was under review in 2009. Professional society guidelines and position statements were also reviewed. In general, the input supported the use of PSG, portable sleep monitoring tests, multiple sleep latency test, and CPAP for adults as described in the policy. The update included the reviewer's recommendations for clarifications and modifications to the policy statements.

Practice Guidelines and Position Statements

American Academy of Sleep Medicine

AASM (2017) published clinical practice guidelines on diagnostic testing for adult OSA.[24] AASM provided the following recommendations (Table 4).

Table 4. Recommendations on Diagnostic Testing for Adult OSA

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

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

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

The AASM also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA.[25] The levels of recommendation are “standard” (generally accepted patient-care strategy, with high degree of certainty; level 1 to 2 evidence), “guideline” (moderate degree of clinical certainty; level 2 to 3 evidence), or “option” (uncertain clinical use; insufficient or inconclusive evidence).

Diagnosis

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

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

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

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

The AASM and the American Academy of Dental Sleep Medicine (2015) published guidelines on the treatment of OSA and snoring with oral appliance therapy.[11] The two societies provided a recommendation of “standard” that sleep physicians consider prescription of oral appliances, rather than no treatment, for adults with OSA who are intolerant of CPAP therapy or prefer alternative therapy. The quality of evidence was rated as moderate. “Guideline” recommendations were provided for the use of custom, titratable appliance over noncustom oral devices, that qualified dentists provide oversight, that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, and that patients return for periodic office visits with a qualified dentist and a sleep physician.

The AASM (2011) published evidence-based guidelines for respiratory indications for PSG in children.[26] “Standard” recommendations were made for the following: PSG in children should be performed and interpreted in accordance with the AASM Manual for the Scoring of Sleep and Associated Events; PSG is indicated when the clinical assessment suggested the diagnosis of OSA in children; children with mild OSA preoperatively should have clinical evaluation following adenotonsillectomy to assess for residual symptoms. If there are residual

symptoms of OSA, PSG should be performed; PSG was indicated following adenotonsillectomy to assess for residual OSA in children with preoperative evidence for moderate-to-severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, and neurologic disorders; PSG was indicated for positive airway pressure titration in children with OSA.

The AASM (2017) published a position statement on the clinical use of a home sleep apnea test.[27] AASM indicated that a home sleep apnea test should be ordered by a physician after "a face-to-face examination" to diagnose OSA or evaluate treatment efficacy and should not be used for general screening of asymptomatic populations. AASM supported the review of "raw data" and interpretation by a "physician board-certified in sleep medicine", stating that automatically scored data "could lead to suboptimal care that jeopardizes patient health and safety".

American Academy of Pediatrics

The American Academy of Pediatrics (AAP; 2012) published guidelines on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting, which updated AAP's 2002 guidelines.[28,29] AAP recommended that all children or adolescents be screened for snoring, and PSG be performed in children or adolescents with snoring and symptoms or signs of OSA as listed in the guideline. If PSG is not available, an alternative diagnostic test or referral to a specialist, may be considered (option). The estimated prevalence rates of OSA in children or adolescents ranged from 1.2% to 5.7%. Adenotonsillectomy was recommended as the first-line treatment for patients with adenotonsillar hypertrophy, and patients should be reassessed clinically postoperatively to determine whether additional treatment is required. High-risk patients should be reevaluated with an objective test or referred to a sleep specialist. CPAP was recommended if adenotonsillectomy was not performed or if OSA persisted postoperatively. Weight loss was recommended in addition to other therapy in patients who are overweight or obese, and intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

American College of Physicians

The guidelines on the diagnosis of OSA in adults from the American College of Physicians (ACP; 2014)) recommended that clinicians target their assessment of OSA to individuals with unexplained daytime sleepiness.[30] ACP recommended PSG for diagnostic testing in patients suspected of OSA, and portable sleep monitors in patients without serious comorbidities as an alternative to PSG when PSG is not available for diagnostic testing (weak recommendation, moderate-quality evidence). Inconclusive areas of evidence included preoperative screening for OSA, phased testing for the diagnosis of OSA, and the utility of portable monitors for diagnosis OSA in patients with comorbid conditions.

The ACP (2013) guidelines on the management of OSA in adults recommended that all overweight and obese patients diagnosed with OSA be encouraged to lose weight (strong recommendation, low-quality evidence).[31] ACP recommended CPAP as initial therapy for patients diagnosed with OSA (strong recommendation; moderate-quality evidence), and mandibular advancement devices as an alternative therapy to CPAP for patients diagnosed with OSA who prefer mandibular advancement devices or for those with adverse effects associated with CPAP (weak recommendation, low-quality evidence).

American Academy of Craniofacial Pain

The American Academy of Craniofacial Pain (AACP) published a position paper in 2013.[32] It indicated that oral appliance therapy was recognized as an effective therapy for many with primary snoring and mild-to-moderate OSA, as well as those with more severe OSA who cannot tolerate PAP therapies, but that oral appliance therapy has the potential to cause adverse effects, including temporomandibular joint pain and dysfunction. The Academy recommended that dentists engaged in, or who want to engage in, the assessment and management of patients with snoring and OSA using mandibular advancement oral appliances should be properly trained and experienced in the assessment, diagnosis and management of temporomandibular joint and craniofacial pain.

American Society of Metabolic and Bariatric Surgery

The American Society of Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA (reviewed in October 2015).[33] The guidelines noted that while some reports in the literature have recommended routine screening for OSA prior to bariatric surgery, other reports have suggested clinical screening only does not result in any increase in postoperative pulmonary complications after laparoscopic Roux-en-Y gastric bypass, and that most current surgical practices refer patients with clinical symptoms of OSA for PSG, but do not make this a routine preoperative test prior to bariatric surgery. The society provided, based on the evidence in the literature to date, the following guidelines on OSA in the bariatric surgery patient and its perioperative management:

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

American Academy of Otolaryngology–Head and Neck Surgery

The American Academy of Otolaryngology – Head and Neck Surgery (2011) published guidelines on PSG for sleep-disordered breathing prior to tonsillectomy in children, which included the following:[34]

1. "Before determining the need for tonsillectomy, the clinician should refer children with SDB [sleep-disordered breathing] for PSG if they exhibit the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses.
2. The clinician should advocate for PSG prior to tonsillectomy for SDB in children *without* any of the comorbidities [listed above] for whom the need for surgery is uncertain or when there is discordance between tonsillar size of physical examination and the reported severity of SDB
3. Clinicians should communicate PSG results to the anesthesiologist prior to the induction of anesthesia for tonsillectomy in a child with SDB.
4. Clinicians should admit children with OSA documented on PSG for inpatient, overnight monitoring after tonsillectomy if they are younger than age 3 years or have severe OSA (apnea-hypopnea index of 10 or more obstructive events/hour, oxygen saturation nadir less than 80%, or both).
5. In children for whom PSG is indicated to assess SDB prior to tonsillectomy, clinicians should obtain laboratory-based PSG, when available."

American Thoracic Society
The American Thoracic Society (2016) published a statement on the long-term effects and treatment of mild OSA in adults.[35] The Society's systematic review concluded:

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

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (2017) reviewed the evidence on screening for OSA in adults and concluded that "the current evidence is insufficient to assess the balance and harms of screening for obstructive sleep apnea (OSA) in asymptomatic adults. Evidence on screening tools to accurately detect persons in asymptomatic populations who should receive further testing and treatment of subsequently diagnosed OSA to improve health outcomes is lacking, and the balance of benefits and harms cannot be determined."[36,37]

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov identified over 300 studies on diagnosis and medical management of OSA.

Government Regulations

National:

National Coverage Determination (NCD) for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1)
Effective Date of this Version 3/3/2009
Implementation Date 8/10/2009

Indications and Limitations of Coverage

B. Nationally Covered Indications
Effective for claims with dates of service on and after March 3, 2009, the Centers for Medicare & Medicaid Services finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a) (1) (A) of the Social Security Act.

1. Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
3. Type IV sleep testing devices measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and

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

C. Nationally Non-Covered Indications
Effective for claims with dates of services on and after March 3, 2009, other diagnostic sleep tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP and are not covered.

Revision History
07/2009 - Previously, although CPAP was nationally covered for beneficiaries with OSA if diagnosed with specific tests, coverage of the tests themselves was left to local contractor discretion. As a result of this recent NCD, effective for claims with dates of service on and after March 3, 2009, Medicare will allow for coverage of the sleep testing devices, specifically: Type 1 PSG when the test is attended in a sleep lab facility, Type II or Type III if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility, or Type IV measuring 3 or more channels, one of which is airflow, if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility. Effective Date: 03/03/2009 Implementation Date: 08/10/2009 (TN 103) (CR6534)

Local:

Wisconsin Physicians Service Insurance Corporation (WPS)
Local Coverage Determination (LCD): Polysomnography and Other Sleep Studies (L36839)
Original Effective Date: For services performed on or after 02/16/2017
Revision Effective Date: For services performed on or after 11/01/2019

Coverage Indications, Limitations, and/or Medical Necessity
Sleep Studies and Polysomnography (PSG) refers to the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep furnished in a sleep laboratory facility that includes physician review, interpretation and report. A technologist is physically present to supervise the recording during sleep time and has the ability to intervene, if needed. The studies are performed to diagnose a variety of sleep disorders and to evaluate a patient's response to therapies such as continuous positive airway pressure (CPAP). PSG is distinguished from sleep studies by the inclusion of sleep staging.

Please refer to CMS publication 100-02 *Medicare Benefit Policy Manual*, Chapter 15 Covered Medical and Other Health Services, Section 70 Sleep Disorder Clinics for guidance: sleep disorder clinics may be hospital-affiliated or freestanding clinics, for conditions diagnosed through the study of sleep, therapy and research which are covered under Medicare.
Polysomnography Testing
Polysomnography (PSG) includes sleep staging, which requires items 1 through 3 below. Polysomnography is defined to minimally include, but is not limited to, the following:
1. A 1-4 lead electroencephalogram (EEG) to measure global neural encephalographic activity using electrodes placed on the scalp.
2. Electrooculogram (EOG) to measure eye movements using electrodes placed near the outer canthus of each eye.

3. A submental electromyogram (EMG) to measure submental electromyographic activity using electrodes placed over the mentalis, submentalis muscle, and/or masseter regions.
4. Rhythm electrocardiogram (ECG).
5. Nasal and/or oral airflow via both thermistor and nasal pressure sensor.
6. Respiratory effort by chest-wall and abdominal movement measured using respiratory inductive plethysmography, endoesophageal pressure or intercostal EMG.
7. Gas exchange (oxygen saturation [SpO2]) by oximetry or transcutaneous monitoring.
8. Bilateral anterior tibialis muscle activity, motor activity-movement using EMG.
9. Body positions by directly applied sensors or by direct observation.

PSG and other sleep test monitoring devices are generally classified based on the number of biologic sensors applied and physiologic parameters recorded.

A. **Criteria for Coverage of Diagnostic Tests**

Please refer to CMS publication 100-02 *Medicare Benefit Policy Manual*, Chapter 15 Covered Medical and Other Health Services, Section 70 Sleep Disorder Clinics, Subsection A. Criteria for Coverage of Diagnostic Tests and Subsection B. Medical Conditions for Which Testing is Covered.

In order to bill claims for diagnostic tests the reasonable and necessary medical conditions will be covered when listed criteria is met:

• Sleep disorder clinics may be hospital-affiliated or freestanding clinics with physician direction and control. Routine diagnostic sleep testing may be performed in the absence of physician direct supervision.

• Sleep disorder clinics will maintain the attending physician's orders/referrals.

• Documentation will support the medical evidence for the need of diagnostic testing, e.g., the signs, symptoms, concerns, or complaints in order for diagnostic testing to be covered, e.g., physician examinations and laboratory tests.

The Social Security Act 1862(a)(1)(A) does not support duplicative diagnostic testing by the attending physician to the extent the results remain pertinent, as not reasonable and necessary.

B. **Medical Conditions for Which Testing is Covered**

- **Sleep Apnea** - Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation. This is a potentially lethal condition where the patient stops breathing during sleep. Three types of sleep apnea have been described (central, obstructive, and mixed). The nature of the apnea episodes can be documented by appropriate diagnostic testing.

Diagnostic testing is covered only if the patient has the symptoms or complaints of one of the conditions listed below.

1. **Obstructive Sleep Apnea (OSA)** is the collapse of the oropharyngeal walls and the obstruction of airflow occurring during sleep. CMS PUB *100-03 NCD* Chapter 1, Section 240.4.1 – Sleep Testing for Obstructive Sleep Apnea (OSA) finds that the evidence is sufficient

to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA.

a. **Type I PSG** is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
   - The most comprehensive is designated Type I attended facility based polysomnography (PSG), which is considered the reference standard for diagnosing OSA. Attended facility based polysomnogram is a comprehensive diagnostic sleep test including at least electroencephalography (EEG), electro-oculography (EOG), electromyography (EMG), heart rate or electrocardiography (ECG), airflow, breathing/respiratory effort, and arterial oxygen saturation (SaO2) furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed.
   - Overnight PSG is the conventional diagnostic test for OSA. The American Thoracic Society and the American Academy of Sleep Medicine have recommended supervised PSG in the sleep laboratory over 2 nights for the diagnosis of OSA and the initiation of continuous positive airway pressure (CPAP).

b. **Type II sleep testing devices** are covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
   - Type II monitors have a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, breathing/respiratory effort, SaO2)-this type of device monitors sleep staging, so AHI can be calculated).

c. **Type III sleep testing devices** are covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
   - Type III monitors have a minimum of 4 monitored channels including ventilation or airflow (at least two channels of respiratory movement or respiratory movement and airflow), heart rate or ECG, and oxygen saturation.

d. **Type IV sleep testing devices** measuring three or more channels, one of which is airflow, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.
   - Type IV devices may measure one, two, three or more parameters but do not meet all the criteria of a higher category device.
   - Sleep testing devices measuring three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

2. **Narcolepsy** - *This term refers to a syndrome that is characterized by abnormal sleep tendencies, e.g., excessive daytime sleepiness or disturbed nocturnal sleep. Related diagnostic testing is covered if the patient has inappropriate sleep episodes or attacks (e.g., while driving, in the middle of a meal, in the middle of a conversation), amnesiac episodes, or continuous disabling drowsiness.* CMS Publication *100-02, Medicare Benefit Policy Manual*, Chapter 15, Section 70.

- The diagnosis of narcolepsy is usually confirmed by an overnight sleep study (polysomnography) followed by a multiple sleep latency test (MSLT). MSLT involves several 20-minute nap opportunities offered at 2-hour intervals. MSLT objectively assesses sleep

tendency by measuring the number of minutes it takes the patient to fall asleep. Conversely, the maintenance of wakefulness test (MWT) requires the patient to try to stay awake.

- MSLT is the better test for demonstration of sleep-onset REM periods, a determination that is important in establishing the diagnosis of narcolepsy. To insure validity, proper interpretation of the MSLT can only be made following a polysomnography performed on the preceding night.
- The following measurements are normally required to diagnose narcolepsy:
  - Polysomnographic assessment of the quality and quantity of nighttime sleep;
  - Determination of the latency of the first REM episode
  - MSLT; and
  - The presence of REM-sleep episodes.
- Initial polysomnography and MSLT occasionally fail to identify narcolepsy. Repeat polysomnography may be indicated:
  - if the first study is technically inadequate due to equipment failure;
  - if the subject could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;
  - if initiation of therapy or confirmation of the efficacy of prescribed therapy is needed; **or**
  - if the results were inconclusive or ambiguous.

3. **Impotence** – will not be addressed in this LCD. See CMS Publication *100-02, Medicare Benefit Policy Manual*, Chapter 15, Section 70 for coverage of impotence.

4. **Parasomnia** - Parasomnias are a group of conditions that represent undesirable or unpleasant occurrences during sleep. Behavior during these times can often lead to damage to the surroundings and injury to the patient or to others. Parasomnia may include conditions such as sleepwalking, sleep terrors, and rapid eye movement (REM) sleep behavior disorders. In many of these cases, the nature of these conditions may be established by careful clinical evaluation. Suspected seizure disorders as possible cause of the parasomnia are appropriately evaluated by standard or prolonged sleep EEG studies. In cases where seizure disorders have been ruled out and in cases that present a history of repeated violent or injurious episodes during sleep, polysomnography may be useful in providing a diagnostic classification or prognosis.

C. Split-Night Studies

1. For Continuous Positive Airway Pressure (CPAP) titration, a split-night study (initial diagnostic polysomnogram followed by CPAP titration during polysomnography on the same night) is an alternative to one full night of diagnostic polysomnography, followed by a second night of titration for the treatment of obstructive sleep apnea (OSA) if the following criteria are met.

   Continuous Positive Airway Pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

2. A positive test for OSA is established if either of the following criteria using the Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) are met:

- AHI or RDI greater than or equal to 15 events per hour with a minimum of 30 events; **or**
- AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.
  The AHI is equal to the average number of episodes of apnea and hypopnea per hour. The RDI is equal to the average number of respiratory disturbances per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing is at least the number of events that would have been required in a 2-hour period.
- CPAP titration is carried out for more than three hours; **and**
- Polysomnography documents that CPAP eliminates, or nearly eliminates, the respiratory events during REM and NREM sleep.

D. Follow-up polysomnography or a cardio-respiratory sleep study is indicated for the following conditions:

- To evaluate the response to treatment (CPAP, oral appliances or surgical intervention);
- After substantial weight loss has occurred in patients on CPAP for treatment of sleep-related breathing disorders to ascertain whether CPAP is still needed at the previously titrated pressure;
- After substantial weight gain has occurred in patients previously treated with CPAP successfully, who are symptomatic again despite continued use of CPAP, to ascertain whether pressure adjustments are needed; or
- When clinical response is insufficient or when symptoms return despite a good initial response to treatment with CPAP.

E. Home Sleep Testing

- The physician services related to home sleep testing (G0398, G0399 and G0400) are covered for the purpose of testing a patient for the diagnosis of obstructive sleep apnea if the home sleep testing is reasonable and necessary for the diagnosis of the patient's condition, meets all other Medicare requirements, and the physician who performs the service has sufficient training and experience to reliably perform the service.
  (See Physician requirements below) (See Billing and Coding: **POLYSOMNOGRAPHY** and Other Sleep Studies)
- A home sleep test is covered only when it is performed in conjunction with a comprehensive sleep evaluation and in patients with a high pretest probability of moderate to severe obstructive sleep apnea.
- Home sleep testing is not covered for persons with comorbidities (moderate to severe pulmonary disease, neuromuscular disease or congestive heart failure).
- Home Sleep studies are only covered for the diagnosis of Obstructive Sleep Apnea. They are not covered for any other sleep disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders or narcolepsy) or for screening asymptomatic persons.

F. Physician and Technician Requirements for Sleep Studies and Polysomnography Testing:

1. **The physician performing the service must meet one of the following:**
   a. be a diplomate of the American Board of Sleep Medicine (ABSM);
      OR
   b. has a Sleep Certification issued by **ONE** of the following Boards:
      American Board of Internal Medicine (ABIM),
      American Board of Family Medicine (ABFM),
      American Board of Pediatrics (ABP),
      American Board of Psychiatry and Neurology (ABPN),
      American Board of Otolaryngology (ABOto),
      American Osteopathic Board of Neurology and Psychiatry (AOBNP),
      American Osteopathic Board of Family Medicine, (AOBFP)
      American Osteopathic Board of Internal Medicine, (AOBIM)
      American Osteopathic Board of Ophthalmology and Otorhinolaryngology (AOBOO);
      OR
   c. be an active physician staff member of a credentialed sleep center or laboratory that have active physician staff members meeting the criteria above in **a** or **b**.

2. **Technician Credentials**
   The technician performing the service must meet one of the following:
   - American Board of Sleep Medicine (ABSM),
     Registered Sleep Technologist (RST);
   - Board of Registered Polysomnographic Technologists (BRPT),
     Registered Polysomnographic Technologist (RPSGT);
   - National Board for Respiratory Care (NBRC)
     Certified Pulmonary Function Technologist (CPFT)
     Registered Pulmonary Function Technologist (RPFT)
     Certified Respiratory Therapist (CRT)
     Registered Respiratory Therapist (RRT)

G. Sleep Center or Laboratory Credentials (this is any site or place of service other than patient's home where sleep studies or recordings are performed)

- The sleep facility credentials must be from the American Academy of Sleep Medicine (AASM), inpatient or outpatient; **OR**
- The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sleep specific credentials for Ambulatory care sleep centers; **OR**
- Accreditation Commission for Health Care (ACHC)
- All centers billing sleep studies must maintain proper certification documentation as defined above.
- The sleep clinic 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. This information must be documented and available upon request.
- Sleep disorder clinics may at times render therapeutic as well as diagnostic services. CMS Publication *100-02, Medicare Benefit Policy Manual*, Chapter 15, Section 70, D. Coverage of Therapeutic Services

Non-covered Services

A. **Polysomnography for Chronic Insomnia Is Not Covered.**
The use of polysomnography for diagnosis of patients with chronic insomnia is not covered under Medicare because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

B. **Actigraphy Testing:**
Actigraphy measures movement of a limb.
It can be measured as part of a sleep test but will not be paid for separately.

C. **Polysomnography or a MSLT is not covered in the following situations:**
1. for the diagnosis of patients with chronic insomnia;
2. to preoperatively evaluate a patient undergoing a laser assisted uvulopalatopharyngoplasty without clinical evidence that obstructive sleep apnea is suspected;
3. to diagnose chronic lung disease (Nocturnal hypoxemia in patients with chronic, obstructive, restrictive, or reactive lung disease is usually adequately evaluated by oximetry. However, if the patient's symptoms suggest a diagnosis of obstructive sleep apnea, polysomnography is considered medically necessary);
4. in cases where seizure disorders have not been ruled out;
5. in cases of typical, uncomplicated, and non-injurious parasomnias when the diagnosis is clearly delineated;
6. for patients with epilepsy who have no specific complaints consistent with a sleep disorder;
7. for patients with symptoms suggestive of the periodic limb movement disorder or restless leg syndrome unless symptoms are suspected to be related to a covered indication;
8. for the diagnosis of insomnia related to depression;
9. for the diagnosis of circadian rhythm sleep disorders (i.e., rapid time-zone change [jet lag], shift-work sleep disorder, delayed sleep phase syndrome, advanced sleep phase syndrome, and non 24-hour sleep wake disorder).

CGS Administrators, LLC
Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611)
Original Effective Date: For services performed on or after 10/1/15
Revision Effective Date: For services performed on or after 01/01/2020

A custom fabricated mandibular advancement oral appliance (E0486) used to treat obstructive sleep apnea (OSA) is covered if criteria A - D are met.

A. The beneficiary has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the beneficiary for obstructive sleep apnea testing.
B. The beneficiary 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 5 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> 30 or the RDI> 30 and meets either of the following (a or b):

a. The beneficiary 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 a 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).

If all of these criteria (A-D) are not met, the custom fabricated oral appliance (E0486) will be denied as not reasonable and necessary.

Refer to the NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the Policy Article for information about coverage for appliances that achieve their effect through positioning of the tongue (A9270).

A prefabricated oral appliance (E0485) will be denied as not reasonable and necessary. There is insufficient evidence to show that these items are effective therapy for OSA.

Custom fabricated mandibular advancement devices that have not received a written coding verification from the Pricing, Data Analysis, and Coding (PDAC) contractor will be denied as not reasonable and necessary.

CGS Administrators, LLC
Local Coverage Article: Oral Appliances for Obstructive Sleep Apnea - Policy Article (A52512)
Original Effective Date 10/01/2015; Revision Effective Date 04/03/2020

Oral appliances used to treat obstructive sleep apnea (OSA) are covered under the Durable Medical Equipment benefit (SSA 1861(s) (6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that must be met.

Oral appliances generally are classified as dental devices and are not classified as durable medical equipment. The following items (not all-inclusive) are considered to be dental devices and will be denied as non-covered, not DME:

- Oral occlusal appliances used to treat temporomandibular joint (TMJ) disorders
- Tongue retaining devices used to treat OSA and/or snoring
- All oral appliances used only to treat snoring without a diagnosis of OSA
- Oral appliances used to treat other dental conditions
- Oral appliances that require repeated fitting and/or adjustments, beyond the first 90-days, in order to maintain fit and/or effectiveness

All follow-up care, including fitting, adjustments, modifications, professional services (not all-inclusive) required during the first 90 days after provision of the oral appliance are considered to be included in the payment for device. Claims for these will be denied as not separately payable.

After the initial 90-day period, adjustments, modifications and follow-up visits are not eligible for coverage under the DME benefit and are therefore not within the jurisdiction of the DME MAC.

Repairs are covered for items that meet the coverage criteria. To repair means to fix or mend and to put the item back in good condition after damage or wear. Repairs are covered when necessary to make the item serviceable. If the expense for repairs exceeds the estimated expense of purchasing another item, no payment can be made for the excess.

Oral appliances are eligible for replacement at the end of their 5-year reasonable useful lifetime (RUL). These items may be replaced prior to the end of the 5-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 be denied as statutorily non-covered prior to the expiration of the 5-year RUL.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Actigraphy
- Home Cardiorespiratory Monitoring - Pediatric
- Obstructive Sleep Apnea and Snoring, Surgical Management
- Positive Pressure Airway Devices

References

1. Somers VK, White DP, Amin R, et al. Sleep apnea and cardiovascular disease: an American Heart Association/American College Of Cardiology Foundation Scientific Statement from the American Heart Association Council for High Blood Pressure Research Professional Education Committee, Council on Clinical Cardiology, Stroke Council, and Council On Cardiovascular Nursing. In collaboration with the National Heart, Lung, and Blood Institute National Center on Sleep Disorders Research (National Institutes of Health). Circulation. Sep 2 2008;118(10):1080-1111. PMID 18725495
2. Kushida CA, Littner MR, Morgenthaler T, et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. Sleep. Apr 1 2005;28(4):499-521. PMID 16171294
3. Zaharna M, et al. A case of positional central sleep apnea. J Clin Sleep Med. 2013;9(3):265-268.
4. Balk EM, Moorthy D, Obadan NO, et al. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32 (Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-100551) AHRQ Publication No. 11-EHC052-EF. Rockville MD: Agency for Healthcare Research and Quality Jul 2011.
5. Corral J, Sanchez-Quiroga MA, Carmona-Bernal C, et al. Conventional Polysomnography Is Not Necessary for the Management of Most Patients with Suspected Obstructive Sleep Apnea. Noninferiority, Randomized Controlled Trial. Am J Respir Crit Care Med. Nov 1 2017;196(9):1181-1190. PMID 28636405
6. Mulgrew AT, Fox N, Ayas NT, et al. Diagnosis and initial management of obstructive sleep apnea without polysomnography: a randomized validation study. Ann Intern Med. Feb 6 2007;146(3):157-166. PMID 17283346

7. Senn O, Brack T, Russi EW, et al. A continuous positive airway pressure trial as a novel approach to the diagnosis of the obstructive sleep apnea syndrome. Chest. Jan 2006;129(1):67-75. PMID 16424414
8. Berry RB, Hill G, Thompson L, et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. Sleep. Oct 1 2008;31(10):1423-1431. PMID 18853940
9. Ayappa I, Norman RG, Seelall V, et al. Validation of a self-applied unattended monitor for sleep disordered breathing. J Clin Sleep Med. Feb 15 2008;4(1):26-37. PMID 18350959
10. Hilmisson H, Berman S, Magnusdottir S. Sleep apnea diagnosis in children using software-generated apnea-hypopnea index (AHI) derived from data recorded with a single photoplethysmogram sensor (PPG): Results from the Childhood Adenotonsillectomy Study (CHAT) based on cardiopulmonary coupling analysis. Sleep Breath. Mar 28 2020. PMID 32222900
11. Ramar K, Dort LC, Katz SG, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. J Clin Sleep Med. Jul 2015;11(7):773-827. PMID 26094920
12. Johal A, Haria P, Manek S, et al. Ready-made versus custom-made mandibular repositioning devices in sleep apnea: a randomized clinical trial. J Clin Sleep Med. Feb 15 2017;13(2):175-182. PMID 27784410
13. van Maanen JP, et al. The sleep position trainer: a new treatment for positional obstructive sleep apnea. Sleep Breath. 2013 May;17(2):771-9.
14. Eijsvogel MM, et al. Sleep position trainer versus tennis ball technique in positional obstructive sleep apnea syndrome. J Clin Sleep Med 2015;11(2):139–147.
15. de Ruiter MHT, et al. Durability of treatment effects of the Sleep Position Trainer versus oral appliance therapy in positional OSA: 12-month follow-up of a randomized controlled trial. Sleep Breath. 2018 May; 22(2):441-450.
16. Singh GD, Griffin T, Cress SE. Biomimetic oral appliance therapy in adults with severe obstructive sleep apnea. J Sleep Disord Ther. 2016;5:1. PMID
17. Singh GD, Cress SE. Biomimetic oral appliance therapy in adults with mild to moderate obstructive sleep apnea using combined maxillo-mandibular correction. J Sleep Disord Manag. 2017;3:014. PMID
18. Krakow B, Ulibarri V, Melendrez D, et al. A daytime, abbreviated cardio-respiratory sleep study (CPT 95807-52) to acclimate insomnia patients with sleep disordered breathing to positive airway pressure (PAP-NAP). J Clin Sleep Med. Jun 15 2008;4(3):212-222. PMID 18595433
19. Berry RB, Kryger MH, Massie CA. A novel nasal expiratory positive airway pressure (EPAP) device for the treatment of obstructive sleep apnea: a randomized controlled trial. Sleep. Apr 2011;34(4):479-485. PMID 21461326
20. Kryger MH, Berry RB, Massie CA. Long-term use of a nasal expiratory positive airway pressure (EPAP) device as a treatment for obstructive sleep apnea (OSA). J Clin Sleep Med. Oct 15 2011;7(5):449-453B. PMID 22003339
21. Riaz M, Certal V, Nigam G, et al. Nasal expiratory positive airway pressure devices (Provent) for OSA: a systematic review and meta-analysis. Sleep Disord. 2015;2015:734798. PMID 26798519
22. Kureshi SA, Gallagher PR, McDonough JM, et al. Pilot study of nasal expiratory positive airway pressure devices for the treatment of childhood obstructive sleep apnea syndrome. J Clin Sleep Med. 2014;10(6):663-669. PMID 24932147
23. Lai V, Tong BK, Tran C, et al. Combination therapy with mandibular advancement and expiratory positive airway pressure valves reduces obstructive sleep apnea severity. Sleep. Aug 01 2019; 42(8). PMID 31180512

24. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. Mar 15 2017;13(3):479-504. PMID 28162150
25. Epstein LJ, Kristo D, Strollo PJ, Jr., et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. J Clin Sleep Med. Jun 15 2009;5(3):263-276. PMID 19960649
26. Ramar K, Dort LC, Katz SG, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. J Clin Sleep Med. Jul 2015;11(7):773-827. PMID 26094920
27. Aurora RN, Zak RS, Karippot A, et al. Practice parameters for the respiratory indications for polysomnography in children. Sleep. Mar 2011;34(3):379-388. PMID 21359087
28. Rosen IM, Kirsch DB, Chervin RD, et al. Clinical Use of a Home Sleep Apnea Test: An American Academy of Sleep Medicine Position Statement. J Clin Sleep Med. Oct 15 2017;13(10):1205-1207. PMID 28942762
29. Section on Pediatric Pulmonology - Subcommittee on Obstructive Sleep Apnea Syndrome. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. Apr 2002;109(4):704-712. PMID 11927718
30. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. Sep 2012;130(3):576-584. PMID 22926173
31. Qaseem A, Dallas P, Owens DK, et al. Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. Ann Intern Med. Aug 5 2014;161(3):210-220. PMID 25089864
32. Qaseem A, Holty JE, Owens DK, et al. Management of obstructive sleep apnea in adults: A clinical practice guideline from the American College of Physicians. Ann Intern Med. Oct 1 2013;159(7):471-483. PMID 24061345
33. Spencer J, Patel M, Mehta N, et al. Special consideration regarding the assessment and management of patients being treated with mandibular advancement oral appliance therapy for snoring and obstructive sleep apnea. Cranio. Jan 2013;31(1):10-13. PMID 23461257
34. American Society of Metabolic and Bariatric Surgery (ASMBS) Clinical Issues Committee. Peri-operative management of obstructive sleep apnea. Surg Obes Relat Dis. May-Jun 2012;8(3):e27-32. PMID 22503595
35. Roland PS, Rosenfeld RM, Brooks LJ, et al. Clinical practice guideline: Polysomnography for sleep-disordered breathing prior to tonsillectomy in children. Otolaryngol Head Neck Surg. Jul 2011;145(1 Suppl):S1-15. PMID 21676944
36. Chowdhuri S, Quan SF, Almeida F, et al. An official American Thoracic Society research statement: impact of mild obstructive sleep apnea in adults. Am J Respir Crit Care Med. May 1 2016;193(9):e37-54. PMID 27128710
37. Bibbins-Domingo K, Grossman DC, et al. Screening for obstructive sleep apnea in adults: US Preventive Services Task Force Recommendation Statement. JAMA. Jan 24 2017;317(4):407-414. PMID 28118461
38. Jonas DE, Amick HR, Feltner C, et al. Screening for obstructive sleep apnea in adults: evidence report and systematic review for the US Preventive Services Task Force. JAMA. Jan 24 2017;317(4):415-433. PMID 28118460
39. Centers for Medicare & Medicaid Services (CMS), Medicare Coverage Database. National Coverage Determination (NCD) for Sleep Testing for Obstructive Sleep Apnea (OSA). Manual Section Number 240.4.1, original date 3/3/09.

40. Wisconsin Physicians Service Insurance Corporation, Local Coverage Determination (LCD): Polysomnography and Other Sleep Studies (L36839), original effective date 2/16/17, revision effective date 11/01/2019.
41. CGS Administrators, LLC, Local Coverage Determination (LCD): Oral Appliances for Obstructive Sleep Apnea (L33611; previous L28603), original effective date 10/01/15, revision effective date 01/01/2020.
42. Mogell K, et al. Definition of an effective oral appliance for the treatment of obstructive sleep apnea and snoring: an update for 2019. Journal of Dental Sleep Medicine. 2019;6(3).

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 12/2/20, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/10/02	7/10/02	7/10/02	Joint policy established
2/27/03	2/27/03	3/4/03	Criteria updated
4/11/05	4/11/05	4/11/05	Routine review
11/15/05	11/15/05	11/15/05	Code update
7/1/07	6/24/07	6/24/07	Updated policy
1/1/09	10/13/08	10/13/08	Routine maintenance, added home sleep test codes, title change
9/1/09	6/16/09	6/16/09	Code Updates
5/1/10	2/16/10	2/16/10	Code update – 0203T and 0204T added to policy. Updated description, rationale, criteria and references. Policy title changed to “Sleep Disorders, Diagnosis and Medical Management”. Previous title, “Obstructive Sleep Apnea (OSA) Diagnosis and Management”.
5/1/11	2/15/11	3/3/11	Routine maintenance; code update – deleted CPT codes 0203T and 0204T; added CPT codes 95800 and 95801
7/1/13	4/16/13	4/22/13	Routine maintenance, Code updates
8/1/16	4/19/16	5/23/16	• Routine maintenance • Updated all policy sections • Added negative oral pressure therapy – replacing JUMP policy

			"Negative Oral Pressure Therapy for the Treatment of OSA"
			• Moved codes 95801, E0485 & G0400 from established to investigational
			  ○ HST with type IV portable monitor with 3 channels not covered
			  ○ Prefabricated intraoral appliances not covered
			• Removed divergence from BCBSA – now aligned

7/1/17	4/18/17	4/18/17	• Routine maintenance • Description, rationale, Medicare information and references updated
7/1/18	4/17/18	4/17/18	• Routine maintenance • Description/rationale added for nasal EPAP and oral pressure therapy. E/I indications added.
1/1/19	10/16/18	10/16/18	• Routine maintenance • Accreditation language added; responses to AASM input added.
1/1/20	10/15/19		• Routine maintenance • Minimum of 3 channels for testing; updated MPS, inclusions and exclusions • Non-invasive ear and pulse oximeter added to policy (E/I for diagnosis) • Lunoa SPT system (E/I for treatment) • Addition of unexplained nocturia as symptoms • Medicare section updated
1/1/21	10/20/20		Routine maintenance Added Ref 3,10,33
3/1/21	1/5/21		Incorporated IMP "Management of Obstructive Sleep Apnea Syndrome with Oral Appliances"
7/1/21	4/20/21		Exclusions to home sleep studies were updated

Next Review Date: 2nd Qtr, 2022

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 6/1/97	Revised: 6/28/01
BCBSM: 1/1/97	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SLEEP DISORDERS- DIAGNOSIS AND MEDICAL MANAGEMENT

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, policy criteria apply.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.