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Diagnosis and Medical Management of Sleep Related Breathing Disorders

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Related Policies (if applicable)
MED201.049: Polysomnography for Non-Respiratory Sleep Disorders

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Coverage

NOTE 1: See Medical Policy MED201.049 for Polysomnography for Non-Respiratory Sleep Disorders including periodic leg movement.

DIAGNOSIS
UNSUPERVISED STUDIES-INITIAL
A single unattended (unsupervised) sleep study with a minimum of 3 recording channels with the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or alternatively peripheral arterial tone (PAT), oximetry and actigraphy **may be considered medically necessary** in adult patients who have symptoms suggestive of obstructive sleep apnea (OSA) with ANY of the following:

- Observed apneas during sleep; OR
- A combination of at least two of the following (1-5):
  1. Excessive daytime sleepiness, as evidenced by one of the following:
     a. An Epworth Sleepiness Scale greater than 10, or

    b. Inappropriate daytime napping (e.g., during driving, conversation, or eating), or
    c. Sleepiness that interferes with daily activities and is not explained by other conditions;
  2. Habitual snoring, or gasping/choking episodes associated with awakenings;
  3. Unexplained hypertension;
  4. Obesity, defined as a body mass index greater than 30 kg/m^2 in adults;
  5. Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy; **AND**
- No presence of a comorbidity that might alter ventilation or decrease the accuracy of a home sleep study, including, but not limited to heart failure, neuromuscular disease, chronic pulmonary disease, or obesity hypoventilation syndrome.

Unattended (unsupervised) sleep apnea tests that do not meet criteria **are considered not medically necessary.**

Limited channel home sleep apnea testing (HST) devices that are unable to calculate apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) (including but not limited to the SleepImage system) **are considered experimental, investigational and/or unproven.**

Unattended (unsupervised) home sleep studies **are considered experimental, investigational and/or unproven** in children (<18 years of age).

UNSUPERVISED STUDIES-REPEAT

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

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

Repeat unattended (unsupervised) sleep apnea tests that do not meet criteria noted **above are considered not medically necessary.**

SUPERVISED STUDIES FOR ADULTS-INITIAL

Supervised polysomnography (PSG) performed in a sleep laboratory **may be considered medically necessary** as a diagnostic test in patients with ANY of the symptoms suggestive of OSA mentioned under Unsupervised Studies (see above) AND when;

- A previous home study was technically inadequate; OR
- A previous home study failed to establish the diagnosis of OSA in a patient with a high pretest probability of OSA; OR
- Failure of resolution of symptoms or recurrence of symptoms during treatment; OR

- Testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy (see Medical Policy MED201.049 Polysomnography for Non-Respiratory Sleep Disorders including periodic leg movement); OR
- There is presence of a comorbidity that might alter ventilation or decrease the accuracy of a home sleep apnea test, including, but not limited to heart failure, neuromuscular disease, chronic pulmonary disease, or obesity hypoventilation syndrome.

NOTE 2: A split-night study, in which moderate-to-severe OSA is documented during the first portion of the study using PSG, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Description section for additional information).

Facility/laboratory PSG **is considered not medically necessary** when adult patients meet criteria for unattended home sleep apnea tests.

SUPERVISED STUDIES FOR PEDIATRIC PATIENTS-INITIAL

Supervised polysomnography performed in a sleep laboratory **may be considered medically necessary** for pediatric patients (i.e., <18 years of age), who have symptoms suggestive of obstructive sleep apnea (OSA). Symptoms suggestive of OSA include but are not limited to the following:

- Observed apneas during sleep; OR
- Snoring; OR
- Obesity, defined as a body mass index greater than 90th percentile for the weight/ height ratio in pediatric patients; OR
- Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy.

SUPERVISED STUDIES-REPEAT

NOTE 3: This section of the coverage applies to repeat supervised studies AND initial titration studies after an unsupervised study.

A repeated study performed in a sleep laboratory **may be considered medically necessary** under the following circumstances:

- To initiate and titrate continuous positive airway pressure (CPAP) in adult patients who either were not candidates for an unsupervised study or failed an auto-adjusting positive airway pressure (APAP) trial, with confirmed clinically significant OSA defined as those patients who have:
  1. Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 15 events per hour, or
  2. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, documented hypertension, heart disease, or history of stroke; OR
- To initiate and titrate CPAP in children:
  1. In pediatric patients, an AHI or RDI of ≥ 5; or

2. An AHI or RDI ≥1.5 in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity; OR

- Failure of resolution of symptoms or recurrence of symptoms during treatment; OR
- To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices; OR
- To assess efficacy and/or titrate following implantation of a hypoglossal nerve stimulator; OR
- To re-evaluate the diagnosis of OSA and need for continued CPAP, e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued.

Repeat studies requiring supervision performed in a sleep laboratory that do not meet criteria noted above **are considered not medically necessary.**

NOTE 4: Repeat sleep studies (home or attended sleep studies) for a patient with known OSA are not necessary to supply new PAP equipment.

MULTIPLE SLEEP LATENCY TESTING

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

MAINTENANCE OF WAKEFULNESS TESTING

Maintenance of Wakefulness (MWT) testing **is considered experimental, investigational and/or unproven** in the diagnosis of OSA.

PAP-NAP

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

MEDICAL MANAGEMENT

Auto-adjusting Positive Airway Pressure (APAP)

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

- An AHI, RDI, or respiratory event index (REI) of at least 15 events per hour, OR
- An AHI, RDI, or REI of at least 5 events per hour in a patient with excessive daytime sleepiness, unexplained hypertension, heart disease, or stroke; OR
- If there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued.

Continuous Positive Airway Pressure (CPAP)

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

Clinically significant OSA in adult patients:

- An AHI, RDI, or REI ≥15, OR
- An AHI, RDI, or REI ≥5 and ≤14 in a patient with excessive daytime sleepiness, unexplained hypertension, heart disease, or history of stroke.

In pediatric patients:
- An AHI or RDI ≥5, OR
- An AHI or RDI ≥1.5 in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity.

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

Bilevel Positive Airway Pressure for Central Sleep Apna or Complex Sleep Apnea
Bilevel positive airway pressure **may be considered medically necessary** for patients with a diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA).

NOTE 5: This medical policy only addresses bilevel positive airway pressure for obstructive sleep apnea and central sleep apnea or complex sleep apnea. This device may be used for other diagnoses including, but not limited to, restrictive thoracic disorders, severe chronic obstructive pulmonary disease (COPD) and hypoventilation syndromes. These conditions are not addressed in this medical policy.

INTRAORAL APPLIANCES-ADULTS
Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) **may be considered medically necessary** in adult patients with mild to moderate OSA who prefer oral appliances (OA) to CPAP, or who do not respond to CPAP, or are not appropriate candidates for CPAP, that meet ALL of the following conditions:
- The device is prescribed by a treating physician, and
- The device is custom-fitted by qualified dental personnel, **and**

Either:
- MILD OSA: Apnea/hypopnea index (AHI), respiratory disturbance index (RDI) or respiratory event index (REI) greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, documented hypertension, heart disease, or history of stroke, OR
- MODERATE OSA: AHI, RDI or REI greater than or equal to 15 events per hour, but less than or equal to 29 events per hour.

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) **may be considered medically necessary** in adult patients with SEVERE OSA: AHI, RDI or REI greater than 30 events per hour who meet one of the following conditions:
- The patient is not able to tolerate a CPAP device; or

- The use of a CPAP device is contraindicated.

NOTE 6: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for patients with severe OSA, because oral appliances have been shown to be less efficacious in patients with severe OSA than in patients with mild-to-moderate OSA. Therefore, it is particularly important that patients with severe OSA have an initial trial of CPAP and that all reasonable attempts are made to continue treatment with CPAP, prior to the decision to switch to an oral appliance.

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

Oral devices to prevent temporomandibular joint (TMJ) disorders **are considered experimental, investigational and/or unproven.**

INTRAORAL APPLIANCES-PEDIATRIC PATIENTS

Oral appliances **may be considered medically necessary** in the treatment of children with craniofacial anomalies with signs and symptoms of OSA.

Oral appliances **are considered experimental, investigational and/or unproven** for the treatment of OSA in children not meeting the above criteria.

Palate and mandible expansion devices **are considered experimental, investigational and/or unproven** for the treatment of OSA.

Nasal expiratory positive airway pressure and oral pressure therapy devices **are considered experimental, investigational and/or unproven.**

Policy Guidelines

Full correspondence does not exist between CPT codes and the most current categorization scheme for the different types of studies. The 2005 practice parameters from the American Academy of Sleep Medicine list 4 types of monitoring procedures:

- Type 1, standard attended in-lab comprehensive polysomnography (PSG);
- Type 2, comprehensive portable PSG;
- Type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of 4 or more channels of monitoring; and
- Type 4, continuous single or dual bioparameters, consisting of 1 or 2 channels, typically oxygen saturation, or airflow.

Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms “sleep studies” and “PSG” are often used interchangeably. CPT coding distinguishes between sleep studies that do not include

electroencephalographic (EEG) monitoring, and PSG, which includes EEG monitoring. PSG is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the patient's home. There are no specific codes for remotely monitored home sleep studies. They would likely be reported with the CPT code for the sleep study with the GT modifier ("via interactive audio and video telecommunications systems") appended. There is no CPT code for "unattended" PSG.

Cardiorespiratory sleep studies without EEG may be called polygraphic studies and can be attended or unattended by a technologist. CPT codes 95807 and 95806 distinguish polygraphic sleep studies that are attended or unattended, but there are no codes that distinguish between type 3 and type 4 sleep studies. A wide variety of portable monitors and proprietary automated scoring systems are being tested and marketed, but the optimum combination of sensors and scoring algorithms is currently unknown. Current recommendations are that the portable monitoring device have 4 channels (oxygen saturation, respiratory effort, respiratory airflow, heart rate) and permit review of the raw data. Type 4 monitors with fewer than 3 channels are not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional trained in sleep medicine to detect artifacts and data loss.

Description

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

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 (i.e., cars, trucks, heavy equipment), while OSA in children may result in neurocognitive impairment and behavioral problems.

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

Risk Factors For OSA

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

- Habitual snoring;
- Observed apneas;
- Excessive daytime sleepiness;
- 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 (e.g., age of the patient, male gender, thick neck, craniofacial or upper airway soft tissue abnormalities, unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; at present, risk assessment is based primarily on clinical judgment.

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

Diagnosis

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

Split-Night Studies

American Academy of Sleep Medicine practice parameters (2005) have indicated that a split-night study (initial diagnostic PSG followed by CPAP titration during PSG on the same night) is an alternative to 1 full night of diagnostic PSG followed by a second night of titration if the following 4 criteria are met:

1. An AHI of at least 40 events per hour is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI between 20 and 40 events per hour, based on clinical judgment (e.g., if there are also repetitive long obstructions and major desaturations). However, at AHI values below 40, determination of CPAP-level requirements, based on split-night studies, may be less accurate than in full-night calibrations.
2. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).
3. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM sleep, including REM sleep with the patient in the supine position.
4. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder is confirmed, but criteria b and c are not met.

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 3% or 4% arterial oxygen desaturation (depending on criteria) 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 an 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 increasing respiratory effort, terminating in an 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 and 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; CPAP: continuous 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.

OSA In Children

The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a BMI greater than the 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 ≥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.

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.

Bariatric Surgery Patients

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

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

Treatment

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure therapy (i.e., fixed CPAP, bilevel positive airway pressure, or auto-adjusting positive airway pressure) during sleep. This medical policy, 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.

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.

Surgical management of OSA (i.e., uvulopalatopharyngoplasty, orthognathic surgery) is discussed in SUR706.009 Sleep Related Breathing Disorders: Surgical Management.

Specialist Training

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

Medical professionals who interpret a polysomnogram or home sleep study should be trained in sleep medicine and should review the raw data from PSG and home sleep studies to detect artifacts and data loss. In addition, the treatment of patients diagnosed with OSA should be initiated and monitored by a professional trained in sleep medicine. It is important to monitor symptoms and adherence to positive airway pressure treatment (e.g., review of symptoms and device utilization at 90 days with a minimum of 4 hours per night for at least 5 nights per week).

Multiple Sleep Latency Test

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

Regulatory Status

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

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

Novel devices for OSA diagnosis and treatment are described in Table 2.

Table 2. Novel Devices for OSA Diagnosis and Treatment

Device	Manufacturer	Description	FDA Marketing Clearance	FDA Product Code	Year
Diagnosis					
SleepImage System	MyCardio	Software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor to aid in the evaluation of sleep disorders.	K163696	MNR	2017
Treatment					
Provent®	Ventus Medical	Nasal expiratory resistance valve.	K102404	OHP	2010
Winx™		Nasal expiratory resistance valve.	K122130	OZR	2012
mRNA Appliance®	BioModeling Solutions	Expandable oral appliance for the treatment of snoring and mild-to-moderate OSA	K130067	LRK	2014

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

Rationale

This medical policy has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 6, 2021.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the 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 studies 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 medical policy is: Do home sleep apnea tests improve the net health outcome in patients with suspected OSA?

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

Populations

The relevant population of interest is patients with suspected OSA.

Interventions

The tests 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 3).

Table 3. 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 (e.g., watching television, sitting quietly in a car, or sitting and talking to someone)	An ESS of ≥10 is considered excessively sleepy. A decrease of 2 points is considered the MID. (3)
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; MID: minimal important difference; 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.

Study Selection Criteria

For the evaluation of clinical validity of home sleep apnea testing, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores).
- Included a suitable reference standard.
- Patient/sample clinical characteristics were described.
- Patient/sample selection criteria were described.

Multichannel Home Sleep Apnea 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. (4) 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 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 3 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 10 or greater, and absence of clinical suspicion of any other sleep pathology. Both groups of patients who were diagnosed with OSA received 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 6-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 2 points on the ESS, home sleep testing was noninferior to in-laboratory PSG.

Subsection Summary: Multichannel Home Sleep Testing

Based on this evidence and society guidelines, portable monitoring with a minimum of 4 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 the 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. (6) They developed a diagnostic algorithm that had a 94% positive predictive value 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 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 empirical approach, using a 2-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 2-week trial, patients were asked to rate the perceived

effect of treatment and to indicate whether they had used CPAP for more than 2 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 FOSQ 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 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 excluded from analysis.

SleepImage System

The SleepImage System is a cloud-based software 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, while 439 did not. Concordance between the SleepImage-derived AHI and PSG-derived AHI in the successful recordings is shown in Table 4. 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 in a sleep laboratory 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 4. 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) (10)	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)

AHI: apnea/hypopnea index, CI: confidence interval.

Subsection Summary: Limited Channel Home Sleep Apnea Testing

The evidence for limited channel home sleep apnea 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 medical policy is: Does management with PAP, oral appliances, or novel OSA treatments improve the net health outcome in patients who have OSA?

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

Populations

The relevant population of interest is patients with OSA.

Interventions

The therapy being considered is the medical management of OSA in adults, which may include the use of various types of positive airway pressure therapy (i.e., fixed CPAP, bilevel positive airway pressure, or APAP) during sleep.

CPAP involves the administration of air, usually through the nose, by an external device at a fixed- pressure to maintain the patency of the upper airway. Bilevel positive airway pressure is similar to CPAP, but these devices are capable of generating 2 adjustable pressure levels for inspiration and expiration. APAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been

hypothesized that both bilevel positive airway pressure and APAP are more comfortable for the patient and thus might improve patient compliance or acceptance.

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

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 mRNA 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 gradually expand the upper and lower jaw and airway 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: CPAP or its variants. The major limitation of PAP 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 Saturation Index on PSG and improvement in a measure of sleepiness such as the ESS or FOSQ (see Table 3), which are typically conducted within weeks or months.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Positive Airway Pressure Devices

The American Academy of Sleep Medicine (AASM) commissioned a task force (Patil et al. [2019]) to conduct an updated systematic review and meta-analysis of studies for the AASM (2019) guidelines on PAP for the treatment of OSA. (11, 12) Meta-analyses of 184 studies indicated that PAP use leads to clinically significant reductions in disease severity (−23 events/h; 95% CI: −29 to −18 events/h), both subjective and objective sleepiness, daytime and nighttime blood pressure, and motor vehicle accidents, and improved sleep-related QOL. The overall quality of evidence for the outcome of sleepiness was high and the overall quality of evidence for sleep-related QOL and for blood pressure was moderate. The quality of evidence on the effect of PAP on cardiovascular events and mortality was low to moderate, with benefits reported in nonrandomized studies but not in RCTs. The task force concluded that the potential benefits of CPAP outweighed the harms in symptomatic patients. PAP initiation in the home had equivalent effects on patient outcomes compared to in-laboratory titration, and there were no clinically
significant differences in patient outcomes with the use of auto-adjusting or bilevel PAP compared with standard continuous PAP. PAP adherence was improved with the use of educational, behavioral, troubleshooting, and telemonitoring interventions.

The review by Balk et al. (2011) for AHRQ concluded that the strength of evidence for CPAP for OSA was moderate based on the large magnitude of effect on the intermediate outcomes of the AHI, ESS score, and arousal index, even though there was weak evidence demonstrating an effect of CPAP on clinical outcomes. (4) In addition, reviewers found moderate evidence that APAP and fixed-pressure CPAP result in similar levels of compliance (hours used per night) and treatment effects for patients with OSA. There was moderate evidence that CPAP is superior to mandibular advancement devices in improving sleep study measures.

Evidence-based guidelines from American Academy of Sleep Medicine concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals. (13-16) As indicated in the AHRQ report, increased compliance with APAP devices has not been well-documented in clinical trials. (17-19) Thus, the issues associated with APAP are similar to those for bilevel PAP.

Yu et al. (2017) conducted a meta-analysis assessing the association between PAP and cardiovascular events and death. (20) They included 10 trials with a total of 7266 patients with sleep apnea. There were 356 major adverse cardiovascular events and 613 deaths observed during follow-up (range, 6-57 months). The analysis found no significant association of PAP with a composite outcome of acute coronary syndrome events, stroke, or vascular death (relative risk, 0.77; 95% CI, 0.53 to 1.13). Trials were grouped according to adherence to PAP (<4 vs ≥ 4 h/d), type of sleep apnea (obstructive vs central), and type of PAP (CPAP vs adaptive servo-ventilation). Meta-regression identified no association between PAP with outcomes for different levels of apnea severity, follow-up duration, or adherence to PAP. As reported by McEvoy et al. (2016), the largest trial included in the meta-analysis was the Sleep Apnea Cardiovascular Endpoints RCT, which found no benefit of CPAP on the primary composite outcome of death or hospitalization for cardiovascular events in 2717 adults with moderate-to-severe OSA and cardiovascular disease who were followed for a median of 44 months. (21)

With a mean duration of adherence to CPAP therapy of 3.3 hours per night, CPAP significantly reduced daytime sleepiness (adjusted difference in ESS score, -2.5; 95% CI, -2.8 to -2.2; p<0.001) and improved health-related QOL and mood.

Lisan et al. (2019) reported 11-year follow-up of a cohort of 392 patients from the Sleep Heart Health Study who had obesity and severe OSA. (22) For the 81 patients who were prescribed PAP therapy, the propensity-matched hazard ratio for all-cause mortality was 0.58 (95% CI, 0.35 to 0.96) compared to matched patients who did not receive a prescription for PAP. Survival curves indicated that the difference in mortality appeared six to seven years after initiation of PAP. Exploratory analysis indicated that PAP might also be associated with a lower risk of cardiovascular mortality.

An improvement in postoperative outcomes with CPAP was suggested by Mutter et al. (2014) in a matched comparison of patients with OSA who had been diagnosed prior to surgery (2640 surgeries), those not diagnosed until up to 5 years after surgery (1571 surgeries), and 16,277 surgeries for patients without a diagnosis of OSA over 21 years of available data. (23) In multivariate analysis, the risk of respiratory complications was increased for both diagnosed and undiagnosed OSA patients compared with controls (odds ratio, 2.08; p<0.001). The risk of cardiovascular complications, primarily cardiac arrest and shock, was higher in OSA patients not diagnosed until after surgery (relative risk, 2.20; 95% CI, 1.16 to 4.17; p=0.02), but not in those diagnosed prior to surgery (relative risk, 0.75; 95% CI, 0.43 to 1.28; p=0.29); the difference between groups was statistically significant (p=0.009). There was a significant trend toward a higher risk with increasing OSA severity. Study limitations included the inability to determine whether CPAP was used perioperatively, and, because body mass index could not be determined, potential confounding from the close association between obesity and OSA.

Monitoring of APAP use by daily transmission to a web-based database and review by a research coordinator has been shown to improve compliance to positive airway pressure (PAP) therapy (191 min/d vs 105 min/d). (24) For the telemedicine arm of this randomized trial, as reported by Fox et al. (2012), the research coordinator reviewed the transmitted data daily and contacted the patient if any of the following were present: mask leak greater than 40 L/min for more than 30% of the night, less than 4 hours of use for 2 consecutive nights, machine-measured AHI of more than 10 events per hour, and 90th percentile of pressure greater than 16 cm H2O. Evaluation by their physician sleep specialist after 3 months of therapy showed a similar modest decrease in AHI for the 2 groups (1.6 for telemedicine vs 0.7 for controls).

Subsection Summary: Positive Airway Pressure Devices

PAP devices are accepted therapies for OSA. Studies have suggested that both CPAP and APAP are associated with improvements in sleep architecture. Although PAP has been associated with an improvement in intermediate outcomes in multiple studies, it has not been shown to improve hard cardiovascular outcomes. Interpretation of this finding is limited by the duration of follow-up (from 6 to 57 months) and mean CPAP use (<4 hours per night in the largest studies). Eleven-year follow-up of obese patients with severe OSA from the Sleep Heart Health

Study found a reduction in all-cause mortality with PAP use which appeared after six to seven years.

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. (25) Meta-analysis showed that oral appliances reduced the AHI, arousal index, and Oxygen Desaturation Index, and increase 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. (26) 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 apnea test 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 AHI) 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 quality of life 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.

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. (27) All patients had failed to comply with CPAP. Pre- and posttreatment 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. (28) 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.

Subsection Summary: Palate and Mandible Expansion
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.

Daytime sleep study (PAP-NAP)
The PAP-NAP uses a desensitization program to facilitate adaptation to pressurized air and test advanced PAP modes for intolerance to PAP.

Krakow et al. (2008) reported on use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP. (29) 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 1 to 2 hours in bed in which the patient had the opportunity to fall asleep with the mask in place; and posttest 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 PAP-NAP 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.

The same group of investigators (Ulibarri et al., 2020) conducted a retrospective chart review of 139 patients who were diagnosed with OSA or upper airway resistance syndrome between 2011 and 2016 and had initially refused titration of PAP but accepted a trial of PAP with a PAP-NAP. (30) The most common risk factors for initial PAP rejection were depression, insomnia, claustrophobia, and trauma exposure, while the most common indications for PAP-NAP were general reluctance, anxiety, and claustrophobia. The procedure averaged about 3 hours, which included 83 ± 30 min of coaching and 107 ± 57 min napping; 99% of patients experienced expiratory pressure intolerance and a majority preferred an alternative PAP mode for the nap

period. Use at follow-up was determined by renewal request for PAP supplies, retitration, clinic appointment or other contact with staff. The duration of use is unclear from the report, but at the time of follow-up 71% of patients who had initially refused PAP were considered users and 29% were non-users.

Subsection Summary: PAP-NAP
The evidence on the PAP-NAP includes 1 comparative trial with historical controls and a case series of patients who were resistant to CPAP titration. These studies do not provide sufficient evidence to form conclusions on the efficacy of this approach in improving compliance with CPAP. The patient population in the comparative study 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.

Nasal Expiratory Positive Airway Pressure
Evidence on nasal expiratory positive airway pressure (EPAP) includes a moderately sized RCT and a systematic review of the Provent device.

Berry et al. (2011) reported on an industry-sponsored multicenter, double-blind, randomized sham-controlled trial of EPAP. (31) 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 uncertainty of the clinical significance of the results.

Kryger et al. (2011), in an open-label extension of the 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. (32) 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 with 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 (total N=920 patients) that had data on pre- and postnasal EPAP. (33) 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. (34) PSG with EPAP or a placebo device showed a significant mean improvement in Obstructive Apnea Index with EPAP (0.6 vs 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). (35) 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: Nasal Expiratory Positive Airway Pressure

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.

Summary of Evidence

Diagnosis

For individuals who have suspected obstructive sleep apnea (OSA) who receive home sleep apnea testing with at least three recording channels, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. RCTs have reported that home sleep 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 continuous positive airway pressure (CPAP) trial to determine the efficacy of treatment. A negative portable monitoring study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or have a positive study but do not respond to CPAP should undergo further evaluation. The evidence is sufficient to determine that the
technology results in a meaningful improvement in the net health outcome.

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

Treatment

For individuals who have OSA who receive positive airway pressure 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 auto-adjusting positive airway pressure (APAP) to evaluate the efficacy and adjust pressure. APAP or bilevel positive airway pressure may also be indicated if the patient is intolerant of CPAP. The evidence is

sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have OSA who receive novel OSA treatments (e.g., palate expansion, expiratory positive airway pressure, oral pressure therapy), the evidence includes an RCT 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 expiratory positive airway pressure devices (EPAP) 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 Apnea/Hypopnea Index, with minor impact on oxygenation, and a decrease in Epworth Sleepiness Scale score. One comparative trial with historical controls used a positive airway pressure nap (PAP-NAP) to reduce resistance to CPAP titration or use. Additional study is needed to evaluate 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.

Practice Guidelines and Position Statements

American Academy of Sleep Medicine

In 2017, the American Academy of Sleep Medicine (AASM) published clinical practice guidelines on diagnostic testing for adult OSA. (36), AASM provided the following recommendations (Table 5).

Table 5. 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.

AASM also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA. (37) 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 the severity of OSA using the following methods (standard):

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

Treatment with positive airway pressure

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

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

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

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

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

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

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

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

AASM and the American Academy of Dental Sleep Medicine (2015) published guidelines on the treatment of OSA and snoring with oral appliance therapy. (25) The 2 societies provided a recommendation of “standard” that sleep physicians consider prescription of OA, rather than no treatment, for adults with OSA who are intolerant of CPAP therapy or prefer alternative therapy. The quality of evidence was rated as moderate. “Guideline” recommendations were provided for the use of custom, titratable appliance over noncustom oral devices, that qualified dentists provide oversight, that sleep physicians conduct follow-up sleep testing to improve or

confirm treatment efficacy, and that patients return for periodic office visits with a qualified dentist and a sleep physician.

American Academy of Pediatrics

The American Academy of Pediatrics (AAP; 2012) published guidelines on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting, which updated AAP's 2002 guidelines. (38, 39) AAP recommended that all children or adolescents be screened for snoring, and PSG is performed in children or adolescents with snoring and symptoms or signs of OSA as listed in the guideline. If PSG is not available, an alternative diagnostic test or referral to a specialist may be considered (option). The estimated prevalence rates of OSA in children or adolescents ranged from 1.2% to 5.7%. Adenotonsillectomy was recommended as the first-line treatment for patients with adenotonsillar hypertrophy, and patients should be reassessed clinically postoperatively to determine whether additional treatment is required. High-risk patients should be reevaluated with an objective test or referred to a sleep specialist. CPAP was recommended if adenotonsillectomy was not performed or if OSA persisted postoperatively. Weight loss was recommended in addition to other therapy in patients who are overweight or obese, and intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

American Society of Metabolic and Bariatric Surgery

The American Society of Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA (reviewed in October 2015). (40) The guidelines noted that while some reports in the literature have recommended routine screening for OSA prior to bariatric surgery, other reports have suggested clinical screening only does not result in any increase in postoperative pulmonary complications after laparoscopic Roux-en-Y gastric bypass, and that most current surgical practices refer patients with clinical symptoms of OSA for PSG, but do not make this a routine preoperative test prior to bariatric surgery. The Society provided, based on the evidence in the literature to date, the following guidelines on OSA in the bariatric surgery patient and its perioperative management:

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

American Academy of Otolaryngology – Head and Neck Surgery

In 2017, the American Academy of Otolaryngology-Head and Neck Surgery published a position statement on the treatment of obstructive sleep apnea. (41) The academy states that tonsillectomy and adenoidectomy is the first line treatment in pediatric OSA. In most adults,

CPAP is the first line treatment. Surgical procedures may be considered when PAP therapy is inadequate.

American Thoracic Society

The American Thoracic Society (2016) published a statement on the long-term effects and treatment of mild OSA in adults. (42) The Society's systematic review concluded:

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

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2017) reported on the evidence assessing 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." (43, 44)

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in May 2021 identified over 300 ongoing studies on diagnosis and medical management of OSA.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	94660, 94762, 95782, 95783, 95800, 95801, 95805, 95806, 95807, 95808, 95810, 95811
HCPCS Codes	A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046, E0470, E0471, E0485, E0486, E0561, E0562, E0601, G0398, G0399, G0400, K1027

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) **does** have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been **changed** since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
06/01/2022	Document updated with literature review. The following changes were made to Coverage: 1) Removed the following bullet from the SUPERVISED STUDIES FOR ADULTS-INITIAL section: Patients do not meet criteria for an unattended home sleep apnea test as described above; 2) Removed APAP from the following section: Bilevel Positive Airway Pressure or APAP for Obstructive Sleep Apnea (OSA); 3) Replaced NOTE 4 with the following: NOTE 4: Repeat sleep studies (home or attended sleep studies) for a patient with known OSA are not necessary to supply new PAP equipment. The following references were added: 3, 30, and 41.

06/15/2021	The following changes were made to Coverage: 1) Clarified Bilevel Positive Airway Pressure headers; 2) Clarified NOTE 5 to address Central Sleep Apnea and Complex Sleep Apnea; 3) Added "Bilevel positive airway pressure may be considered medically necessary for patients with a diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA)". Title changed from: Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome. No references added.
03/15/2021	Document updated with literature review. The following changes were made to Coverage: REVISED: a) type of equipment considered medically necessary when criteria are met for Unsupervised Studies. b) the list of health conditions listed under the Unsupervised Studies section. c) indications noted under Supervised Studies for Adults - Initial section. d) indications for Intraoral Appliances - Adults. ADDED: In Unsupervised studies-Initial section the following was added: Limited channel home sleep apnea testing (HST) devices that are unable to calculate AHI/RDI (including but not limited to the SleepImage system) are considered experimental, investigational and/or unproven. In the Supervised Studies–Repeat section: a) indications for children b) indication to assess efficacy and/or titrate following implantation of a hypoglossal nerve stimulator. In Maintenance of Wakefulness; clarified the statement by adding: in the diagnosis of obstructive sleep apnea (OSA); Added reference to See Medical Policy MED201.049 Polysomnography for Non-Respiratory Sleep Disorders including periodic leg movement. CHANGED: a) Coverage for Bilevel positive airway pressure or Auto-adjusting positive airway pressure (APAP) to the following: Bilevel positive airway pressure or APAP may be considered medically necessary in patients with clinically significant OSA who have failed a prior trial of continuous positive airway pressure (CPAP) or for whom bilevel positive airway pressure is found to be more effective in the sleep lab. b) Under Medical Management section; The use of CPAP, bi-level positive airway pressure, APAP was added to address all devices that do not meet the above criteria are considered experimental, investigational and/or unproven for the treatment of OSA. c) NOTE 5 to address bilevel positive airway pressure associated with OSA. NOTE 2 was added, other NOTES were renumbered. Added references 9-11, 21, 33, 48-50; some references removed.
01/01/2019	New medical document. The following diagnostic services for obstructive sleep apnea syndrome (OSA) may be eligible for coverage when meeting conditional criteria: initial and repeat unsupervised sleep studies and initial and repeat supervised sleep studies. The following services used in the medical management of OSA may be eligible for coverage when meeting conditional criteria: continuous positive airway pressure (CPAP), auto-adjusting positive airway pressure (APAP), bilevel positive airway pressure (BiPAP) with back-up rate feature, and intraoral appliances. Initial and repeat unsupervised sleep apnea tests that do not meet criteria are considered not medically necessary. Unsupervised home sleep studies are considered

	experimental, investigational and/or unproven in children (<18 years of age). Facility/laboratory polysomnography (PSG) is considered not medically necessary when adult patients meet criteria for unattended home sleep apnea tests. Repeat studies requiring supervision performed in a sleep laboratory that do not meet criteria are considered not medically necessary. Multiple sleep latency testing (MSLT) is considered not medically necessary in the diagnosis of OSA. Maintenance of Wakefulness (MWT) testing is considered experimental, investigational and/or unproven. The use of an abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies is considered experimental, investigational and /or unproven. Oral appliances are considered experimental, investigational and/or unproven for the treatment of OSA in adults not meeting criteria. Oral devices to prevent temporomandibular joint (TMJ) disorders are considered experimental, investigational and/or unproven. Oral appliances are considered experimental, investigational and/or unproven for the treatment of OSA in children not meeting criteria. Palate and mandible expansion devices are considered experimental, investigational and/or unproven for the treatment of OSA. Nasal expiratory positive airway pressure and oral pressure therapy devices are considered experimental, investigational and/or unproven.