

Medical Policy



Title: **Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome**

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With suspected obstructive sleep apnea 	Interventions of interest are: <ul style="list-style-type: none"> Home sleep apnea testing with at least 3 recording channels 	Comparators of interest are: <ul style="list-style-type: none"> Polysomnography 	Relevant outcomes include: <ul style="list-style-type: none"> Test accuracy Symptoms Functional outcomes Resource utilization
Individuals:	Interventions of interest are:	Comparators of interest are:	Relevant outcomes include:

Populations	Interventions	Comparators	Outcomes
<ul style="list-style-type: none"> With suspected obstructive sleep apnea 	<ul style="list-style-type: none"> Limited channel home sleep apnea testing 	<ul style="list-style-type: none"> In-laboratory polysomnography Home sleep testing with at least 3 recording channels 	<ul style="list-style-type: none"> Test accuracy Symptoms Functional outcomes Resource utilization
Individuals: <ul style="list-style-type: none"> With obstructive sleep apnea 	Interventions of interest are: <ul style="list-style-type: none"> Positive airway pressure devices 	Comparators of interest are: <ul style="list-style-type: none"> Weight loss Position therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Functional outcomes Quality of life
Individuals: <ul style="list-style-type: none"> With obstructive sleep apnea 	Interventions of interest are: <ul style="list-style-type: none"> Oral appliances 	Comparators of interest are: <ul style="list-style-type: none"> Continuous positive airway pressure therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Functional outcomes Quality of life
Individuals: <ul style="list-style-type: none"> With obstructive sleep apnea 	Interventions of interest are: <ul style="list-style-type: none"> Novel obstructive sleep apnea treatment (eg, palate expansion, expiratory positive airway pressure, oral pressure therapy) 	Comparators of interest are: <ul style="list-style-type: none"> Continuous positive airway pressure therapy 	Relevant outcomes include: <ul style="list-style-type: none"> Symptoms Functional outcomes Quality of life

DESCRIPTION

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

Objective

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

Background

Obstructive Sleep Apnea

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

The hallmark of OSA is snoring. The snoring abruptly ceases during the apneic episodes and during the brief period of patient arousal and then resumes when the patient again falls asleep. The sleep fragmentation associated with repeated sleep disruption can lead to impairment of daytime activity. Adults with OSA-associated daytime somnolence are thought to be at higher risk for collisions involving motorized vehicles (ie, cars, trucks, 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

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.

Table 1. Definitions of Terms and Scoring Criteria for OSA

Terms	Definition
Respiratory event	
Apnea	The frequency of apneas and hypopneas is measured from channels assessing oxygen desaturation, respiratory airflow, and respiratory effort. In adults, apnea is defined as a drop in airflow by 90% or more of pre-event baseline for at least 10 seconds. Due to faster respiratory rates in children, pediatric scoring criteria define an apnea as 2 or more missed breaths, regardless of its duration in seconds.
Hypopnea	Hypopnea in adults is scored when the peak airflow drops by at least 30% of pre-event baseline for at least 10 seconds in association with either at least 4% arterial oxygen desaturation or an arousal. Hypopneas in children are scored by a 50% or greater drop in nasal pressure and either a 3% or more decrease in oxygen saturation or associated arousal.
RERA	Respiratory event-related arousal is defined as an event lasting at least 10 seconds associated with flattening of the nasal pressure waveform and/or evidence of increased respiratory effort, terminating in arousal but not otherwise meeting criteria for apnea or hypopnea
Respiratory event reporting	

Terms	Definition
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 \geq 1.0 to <5
Moderate OSA	AHI or RDI of 15 to < 30; Children: AHI of \geq 5 to <10
Severe OSA	Adults: AHI or RDI \geq 30; Children: AHI of \geq 10
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.
Positive airway pressure	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP
PAP	Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation for delivery of positive airway pressure.
PAP failure	Usually defined as an AHI >20 events per hour while using CPAP
PAP intolerance	CPAP use for <4 hours per night for \geq 5 nights per week, or refusal to use CPAP. CPAP intolerance may be observed in patients with mild, moderate, or severe OSA

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

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

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

Treatment

Medical management of OSA in adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure therapy (ie, fixed CPAP, bilevel positive airway pressure, or auto-adjusting positive airway pressure)

during sleep. This evidence review addresses established and novel devices including the Daytime-Nighttime Appliance (BioModeling Solutions), the mandibular Repositioning Nighttime Appliance (BioModeling Solutions), Provent and Winx. Provent is a single-use nasal expiratory resistance valve device containing valves inserted into the nostrils and secured with adhesive. The Winx system uses oral pressure therapy to treat OSA.

Surgical management of OSA (ie, adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in evidence review 7.01.101 (surgical treatment of snoring and OSA syndrome).

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.

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

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

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

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

POLICY**I. Diagnosis****A. Unattended (unsupervised) Home Sleep Apnea Test**

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

Policy Guideline #2 defines high risk.

2. A single unattended (unsupervised) home sleep apnea test with a minimum of recording channels as described in I A 1 may be considered **medically necessary** as a screening tool in patients who are scheduled for bariatric surgery and have no evidence of a health condition that might alter ventilation or require alternative treatment (see Policy Guideline #3).
3. Unattended home sleep apnea tests are considered **experimental / investigational** in children (<18 years of age).
4. Repeat unattended (unsupervised) home sleep apnea test with a minimum of 3 recording channels with the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or alternatively PAT, oximetry and actigraphy, may be considered **medically necessary** in adults under the following circumstances:
 - a. To assess efficacy of surgery or oral appliances or devices; **OR**
 - b. To reevaluate the diagnosis of OSA and need for continuous positive airway pressure (CPAP), eg, if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued.

B. Supervised Polysomnography (PSG)

1. Supervised polysomnography (PSG) performed in a sleep laboratory may be considered **medically necessary** in patients with a moderate or high risk of OSA in the following situations:
 - a. Pediatric patients (ie, < 18 years of age) **OR**
 - b. When patients do not meet criteria for an unattended home sleep apnea test as described above **OR**
 - c. A previous home study failed to establish the diagnosis of OSA in a patient with a high risk of OSA **OR**
 - d. A previous home study was technically inadequate **OR**
 - e. Failure of resolution of symptoms or recurrence of symptoms during treatment **OR**
 - f. When testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy **OR**
 - g. 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, obesity hypoventilation syndrome

2. A repeated supervised polysomnography (PSG) performed in a sleep laboratory may be considered **medically necessary** in patients who meet criteria in I B 1 for an in-laboratory PSG under the following circumstances:
 - a. To initiate and titrate continuous positive airway pressure (CPAP) in adults who have:
 - i. An Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of at least 15 events per hour, **OR**
 - ii. An AHI or RDI of at least 5 events per hour in a patient with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke)

Note: A split-night study, in which moderate to severe OSA is documented during the first portion of the study using polysomnography, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guideline #7).

- b. To initiate and titrate CPAP in children:
 - i. In pediatric patients, an AHI or RDI of ≥ 5 **OR**
 - ii. An AHI or RDI ≥ 1.5 in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity
 - c. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices

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

- D. The use of an abbreviated daytime sleep study (PAP-NAP) as a supplement to standard sleep studies is considered **experimental / investigational**.
- E. Multiple sleep latency testing is considered **experimental / investigational** in the diagnosis of OSA.

II. Medical Management

- A. Auto-adjusting positive airway pressure (APAP) may be considered **medically necessary** for the titration of pressure in adults with clinically significant OSA defined as those who have:
 - 1. An Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), or Respiratory Event Index (REI) of at least 15 events per hour, **OR**
 - 2. An AHI, RDI, or REI of at least 5 events per hour in a patient with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke); **OR**
 - 3. If there is a significant change in weight or change in symptoms suggesting that continuous positive airway pressure (CPAP) should be reiterated or possibly discontinued.
- B. CPAP may be considered **medically necessary** in adult or pediatric patients with clinically significant OSA
 - 1. Clinically significant OSA in adults is:
 - a. An AHI, RDI, or REI ≥ 15 , **OR**
 - b. An AHI, RDI, or REI ≥ 5 in a patient with one or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).
 - 2. In pediatric patients,
 - a. An AHI or RDI ≥ 5 **OR**
 - b. An AHI or RDI ≥ 1.5 in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity
- C. Bilevel positive airway pressure or APAP may be considered **medically necessary** in patients with clinically significant OSA who have failed a prior trial of CPAP or for whom bilevel positive airway pressure (BiPAP) is found to be more effective in the sleep lab.
- D. Intraoral appliances (tongue-retaining devices or mandibular advancing / positioning devices) may be considered **medically necessary** in adults with clinically significant OSA under the following conditions:
 - 1. OSA, defined by an AHI or REI of at least 15 events per hour or an AHI, RDI, or REI of at least 5 events per hour in a patient with one or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke)
AND

2. A trial with CPAP has failed or is contraindicated
AND
3. The device is prescribed by a treating physician
AND
4. The device is custom-fitted by a dentist or by qualified dental personnel under the supervision of a dentist
AND
5. The patient has been evaluated and cleared by a dentist for the device.

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

- E. The use of CPAP, bi-level positive airway pressure, APAP, and intraoral appliances that do not meet the above criteria is considered **experimental / investigational** for the treatment of OSA.
- F. Palate and mandible expansion devices are considered **experimental /investigational** for the treatment of OSA.
- G. Nasal expiratory positive airway pressure (EPAP) and oral pressure therapy devices are considered **experimental / investigational**.

Policy Guidelines

1. Specialist Training

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

Medical professionals who interpret a polysomnogram or home sleep 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.

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

2. Risk Factors for Obstructive Sleep Apnea

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

- habitual snoring
- observed apneas
- excessive daytime sleepiness
- a body mass index (BMI) greater than 35 kg/m²

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

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

3. **OSA In Children**

The presentation of obstructive sleep apnea (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 Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) greater than 1.5 events per hour is considered abnormal (an AHI or RDI \geq 10 events per hour may be considered severe). In addition, the first-line treatment in children is usually adenotonsillectomy. Continuous positive airway pressure (CPAP) is an option for children who are not candidates for surgery or who have an inadequate response to surgery.

4. **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.

5. **Significant Weight Change**

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

6. **Multiple Sleep Latency Test**

The multiple sleep latency test (MSLT) is an objective measure of the tendency to fall asleep in the absence of alerting factors, while the maintenance of wakefulness test (MWT) is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). The MSLT and MWT are not routinely indicated in the evaluation and diagnosis of OSA or in 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.

7. **Split-Night Studies**

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

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

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 11, 2020.

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other

types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

SUSPECTED OBSTRUCTIVE SLEEP APNEA

Clinical Context and Test Purpose

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

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

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

Patients

The relevant populations of interest is patients with suspected OSA.

Interventions

The 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 2).

Table 2. Health Outcome Measures Relevant to OSA

Outcome	Measure	Description	Clinically Meaningful Difference (If Known)
Change in AHI	AHI	Mean change in AHI from baseline to posttreatment	Change from severe-to-moderate or mild OSA
AHI success	Percentage of patients achieving success	Studies may use different definitions of success, but the most common for AHI success is the Sher criteria	Sher criteria include a decrease in AHI of $\geq 50\%$ 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	An ESS of ≥ 10 is considered excessively sleepy

Outcome	Measure	Description	Clinically Meaningful Difference (If Known)
		likely they are to fall asleep in 8 different situations (eg, watching TV, sitting quietly in a car, or sitting and talking to someone)	
FOSQ	30 questions	Disease-specific quality of life questionnaire that evaluates functional status related to excessive sleepiness	A score of ≥ 18 is the threshold for normal sleep-related functioning, and a change of ≥ 2 points is considered a clinically meaningful improvement

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

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

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

Review of Evidence

Multichannel Home Sleep 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.³ 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 three recording channels that include respiratory effort, airflow, and oxygen saturation, but not heart rate, are considered by some, including the Centers for Medicare & Medicaid, to be sufficient for home sleep apnea tests. 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.⁴ Included in the study were patients referred to tertiary hospitals in Spain for suspected OSA, who had snoring or sleep apneas observed by a partner, ESS score of ten or greater, and absence of clinical suspicion of any other sleep pathology. Both groups of patients who were diagnosed with OSA received continuous positive airway pressure (CPAP) titration with a single APAP session at home. The median baseline ESS score was 13 in both groups. CPAP was indicated in 68% of patients in the PSG arm compared with 53% in the home sleep testing group, with the difference attributed to the underestimation of AHI in-home sleep studies. All patients, including those treated with CPAP and those who were not, were assessed at six-month follow-up. ESS score improved by -4.2 (95% confidence interval [CI], -4.8 to -3.6) in the home sleep testing group and by -4.9 (95% CI, -5.4 to -4.3) in the PSG group. With a noninferiority margin of two points on the ESS, home sleep testing was noninferior to in-laboratory PSG.

Subsection Summary: Multichannel Home Sleep Apnea Testing

Based on this evidence and society guidelines, portable monitoring with a minimum of four recording channels (including oxygen saturation, respiratory movements, airflow, an 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 APNEA 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 APAP.⁵ 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 attend 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.⁶ Patients (n=76) were included in the study if they had been referred by primary care physicians for evaluation of suspected OSA, were habitual snorers, complained of daytime sleepiness, and had an ESS score of 8 or greater (mean, 13.6). At the end of the two-week trial, patients were asked to rate the perceived effect of treatment and to indicate whether they had used CPAP for more than two hours per night and were willing to continue treatment. Patients without a clear benefit of CPAP received further evaluation, including clinical assessment and PSG. Compared with PSG, patient responses showed a sensitivity of 80%, a specificity of 97%, a positive predictive value of 97%, and a negative predictive value of 78%.

Berry et al (2008) randomized 106 patients referred for a sleep study for suspected OSA at a local Veterans Administration center to portable monitoring followed by APAP or to PSG for diagnosis and treatment.⁷ 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.⁸ 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 the analysis.

SleepImage System

The SleepImage System is cloud-based software a medical device that generates AHI from data recorded with a single photoplethysmogram sensor. The SleepImage algorithms calculate heart rate variability, respiration, and oxygen saturation with cardiopulmonary coupling analysis. Hilmisson et al (2020) compared results calculated by the SleepImage System with manually scored PSG in 805 children ages 5 to 9.9 yrs of age who participated in the Childhood Adenotonsillectomy Trial (CHAT).⁹ The CHAT study included 1244 habitually snoring children who were referred for PSG. A total of 805 children had successfully collected data from the sensor. Concordance between the SleepImage-derived AHI and PSG-derived AHI is shown in Table 3. Kappa was 0.81, 0.89, and 0.91 for mild, moderate, and severe sleep apnea, respectively. A proposed benefit is that this would be easier for children compared to a test requiring multiple sensors and improve access. Further study in a wider population is needed to evaluate whether this system might be a suitable method for evaluating sleep parameters in the home.

Table 3 Clinical Validity of the SleepImage System

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

CI: confidence interval.

Subsection Summary: Limited Channel Home Sleep 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 evidence review is: Does management with PAP, oral appliances, or novel OSA treatments improve the net health outcome?

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

Patients

The relevant population of interest is patients with OSA.

Interventions

The therapy being considered is the medical management of OSA in adults, which may include the use of various types of PAP therapy (ie, fixed CPAP, bilevel PAP, 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 PAP is similar to CPAP but these devices are capable of generating two adjustable pressure levels. APAP adjusts the level of pressure based on the level of resistance and thus administers a lower mean level of positive pressure during the night. It has been hypothesized that both bilevel PAP 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. The criterion standard treatment is CPAP or its variants. The major limitation of PAP therapy is poor patient compliance due to the need to wear a face or nasal mask.

Outcomes

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

Review of Evidence

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.^{10,11} 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 non-randomized 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.³ 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 the AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals.^{12,13,14,15} As indicated in the AHRQ report, increased compliance with APAP devices has not been well-documented in clinical trials.^{16,17,18} 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.¹⁹ 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.²⁰ 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.²¹ 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 16277 surgeries for patients without a diagnosis of OSA over 21 years of available data.²² 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).²³ 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 three months of therapy showed a similar modest decrease in AHI for the two 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 AASM and the American Academy of Dental Sleep Medicine.²⁴ Meta-analysis showed that oral appliances reduced the AHI, arousal index, and Oxygen Desaturation Index, and increased oxygen saturation. However, oral appliances had no significant effect on sleep architecture or sleep efficiency. The meta-analysis found CPAP to be more effective than oral appliances in reducing the AHI, arousal index, and Oxygen Desaturation Index, and in improving oxygen desaturation, supporting the use of CPAP as 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.²⁵ 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 three-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 QOL 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.³

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 OBSTRUCTIVE SLEEP APNEA 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.²⁶ All patients had failed to comply with CPAP. Pre- and post-treatment AHI was assessed in a home sleep apnea test without the oral appliance. AHI decreased from a mean 45.9 events per hour to 16.5 ($p<0.01$) after a mean 9.7 months of treatment. Singh et al (2016) and Cress (2017) reported on a series of 19 patients who had mild-to-moderate OSA who were treated with a DNA or mRNA Appliance.²⁷ Only patients who complied with oral appliance wear were included in the study. The mean AHI was reduced from 12.85 to 6.2 events per hour ($p<0.001$) with the appliance, while the Oxygen Saturation Index improved from 6.3% to 2.6% ($p<0.001$). Limitations of these studies included the use of a home sleep apnea test rather than the more accurate laboratory PSG, uncertain blinding of the physician evaluating the sleep study, the small number of patients studied, the lack of intention-to-treat analysis, and the lack of long-term follow-up.

PAP-NAP

Krakov et al (2008) reported on the use of a daytime abbreviated sleep study to acclimate patients with complex insomnia to PAP.²⁸ 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 five components: pretest instructions to maximize chances

for daytime napping; introduction of PAP therapy addressing barriers to use; type 3 monitoring hookup (ten channels without electroencephalography leads); PAP therapy during one to two hours in bed in which the patient had the opportunity to fall asleep with the mask in place; and post-test follow-up. Thirty-five of 39 nap-tested patients subsequently scheduled and completed an overnight titration or split-night study with full PSG. The effect of the PAP-NAP intervention on compliance was compared with historical controls (n=38) who had insomnia, mental health conditions, and OSA with resistance to CPAP who completed titration. A prescription for PAP therapy was filled by 85% of the 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.

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.²⁹ 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 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 three 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 ³10 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.³⁰ 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.³¹ Study designs included ten conference papers and eight 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 the 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.³² 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 (three did not improve, two 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).³³ 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 a an AHI difference of 7 between conditions. Five patients (23%) had at least a 50% reduction in total AHI with the oral EPAP compared to the oral appliance alone, while 10 patients (45%) had a 50% reduction in AHI with the combined oral and nasal EPAP valves. Neither of these was statistically significant. Only 2 patients (9%) achieved an AHI of less than 5 with the oral EPAP device compared to 9 (41%) with the combined oral and nasal valves. However, sleep efficiency was disrupted with the oronasal EPAP valves.

Subsection Summary: Novel Obstructive Sleep Apnea Treatments

The evidence on palate and mandible expansion devices includes a few small cohort studies. Further study with well-designed trials is needed to evaluate this treatment.

The evidence on nasal EPAP devices in patients with OSA has been reported in several prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in AHI with a minor impact on oxygenation

and ESS scores. An oral EPAP device did not have significant benefit when added to an oral appliance.

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

Summary of Evidence

Diagnosis

For individuals who have suspected OSA who receive home sleep apnea testing with at least three recording channels, the evidence includes RCTs. Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. RCTs have reported that home sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone, actigraphy and oxygen saturation) is noninferior to testing in the sleep lab for adults with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation. A positive portable monitoring study with channels that include arterial oxygen saturation, airflow, and respiratory effort has a high positive predictive value for OSA and can be used as the basis for a CPAP trial to determine the efficacy of treatment. A negative portable monitoring study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or have a positive study but do not respond to CPAP should undergo further evaluation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

Treatment

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

For individuals who have OSA who receive novel OSA treatments (eg, palate expansion, EPAP, oral pressure therapy), the evidence includes RCTs and a meta-analysis of case series. Relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on palate and mandible expansion devices includes a few small series. Further study with well-designed trials is needed

to evaluate this treatment. The evidence on nasal EPAP devices in patients with OSA has been reported in prospective case series, an industry-sponsored RCT, and a systematic review that did not include the RCT. The main finding of the RCT was a decrease in the AHI, with minor impact on oxygenation, and a decrease in ESS score. One comparative trial with historical controls used a PAP-NAP to study patients with complex insomnia resistant to CPAP titration or use. Additional study is needed to evaluate with greater certainty the efficacy of this intervention. One small RCT with 22 patients found no benefit of an oral EPAP therapy device when added to an oral appliance. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from 7 physician specialty societies (8 reviewers) and 4 academic medical centers (6 reviewers) while this policy was under review in 2014. Input focused on the routine screening of patients scheduled to undergo bariatric surgery. There was a consensus that routine screening is considered medically necessary in this population due to the high prevalence of obstructive sleep apnea (OSA) in patients with a body mass index greater than 40 kg/m², combined with the increased rate of perioperative complications in patients with OSA. The input was mixed on whether the use of portable home sleep testing was appropriate for patients scheduled for bariatric surgery. Concerns were raised about the high prevalence of obesity hypoventilation syndrome in this population, which is a contraindication to home sleep testing. Other reviewers considered home sleep testing to be appropriate in patients scheduled for bariatric surgery, with the caveat that obesity hypoventilation syndrome should be ruled out prior to home sleep testing.

2010 Input

In response to requests, input was received from 1 physician specialty society and 6 academic medical centers (8 reviewers) while this policy was under review in 2010. Input focused on the sensors required for unattended home sleep studies and on diagnosis and treatment of OSA in children. In general, reviewers supported the requirement that home monitors measure four parameters, including respiratory effort, airflow, and oxygen saturation, and their use is restricted to adults. Some exceptions were noted for specific situations. The 2010 update included recommendations from reviewers on indications specific to pediatric patients.

2009 Input

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

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.³⁴ AASM provided the following recommendations (Table 4).

Table 4. Recommendations on Diagnostic Testing for Adult OSA

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

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

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

The AASM also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA.³⁵ The levels of recommendation are "standard" (generally accepted patient-care strategy, with a high degree of certainty; level 1 to 2 evidence), "guideline" (moderate degree of clinical certainty; level 2 to 3 evidence), or "option" (uncertain clinical use; insufficient or inconclusive evidence).

Diagnosis

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

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

Treatment with positive airway pressure

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

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

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

The AASM (2019) published a clinical practice guideline on the treatment of OSA with positive airway pressure (PAP) that was based on a systematic review of the evidence.^{10,11} "A STRONG (ie, "We recommend...") recommendation is one that clinicians should follow under most circumstances. A CONDITIONAL recommendation (ie, "We suggest...") reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients."

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

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

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

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

The AASM and the American Academy of Dental Sleep Medicine (2015) published guidelines on the treatment of OSA and snoring with oral appliance therapy.²⁴ The two societies provided a recommendation of "standard" that sleep physicians consider prescription of oral appliance, rather than no treatment, for adults with OSA who are intolerant of CPAP therapy or prefer alternative therapy. The quality of evidence was rated as moderate. "Guideline" recommendations were provided for the use of custom, titratable appliance over noncustom oral devices, that qualified dentists provide oversight, that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, and that patients return for periodic office visits with a qualified dentist and a sleep physician.

The AASM (2011) published evidence-based guidelines on respiratory indications for PSG in children.³⁶ "Standard" recommendations were made for the following: PSG in children should be performed and interpreted in accordance with the AASM Manual for the Scoring of Sleep and Associated Events; PSG is indicated when the clinical assessment suggested the diagnosis of OSA in children; children with mild OSA preoperatively should have clinical evaluation following adenotonsillectomy to assess for residual symptoms. If there are residual symptoms of OSA, PSG should be performed; PSG was indicated following adenotonsillectomy to assess for residual OSA in children with preoperative evidence for moderate-to-severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, and neurologic disorders; PSG was indicated for positive airway pressure titration in children with OSA.

The AASM (2017) published a position statement on the clinical use of a home sleep apnea test.³⁷ The AASM indicated that a home sleep apnea test should be ordered by a physician after "a face-to-face examination" to diagnose OSA or evaluate treatment efficacy and should not be used for general screening of asymptomatic populations. The AASM supported the review of raw data and interpretation by a physician board-certified in sleep medicine, stating that automatically scored data "could lead to sub-optimal care that jeopardizes patient health and safety".

American Academy of Pediatrics

The American Academy of Pediatrics (AAP; 2012) published guidelines on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting, which updated the 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 College of Physicians

The guidelines on the diagnosis of OSA in adults from the American College of Physicians (ACP; 2014) recommended that clinicians target their assessment of OSA to individuals with unexplained daytime sleepiness.⁴⁰ The ACP recommended PSG for diagnostic testing in patients suspected of OSA, and portable sleep monitors in patients without serious comorbidities as an alternative to PSG when PSG is not available for diagnostic testing (weak recommendation, moderate-quality evidence). Inconclusive areas of evidence included preoperative screening for OSA, phased testing for the diagnosis of OSA, and the utility of portable monitors for diagnosis OSA in patients with comorbid conditions.

The ACP (2013) guidelines on the management of OSA in adults recommended that all overweight and obese patients diagnosed with OSA be encouraged to lose weight (strong recommendation, low-quality evidence).⁴¹ The ACP recommended CPAP as initial therapy for patients diagnosed with OSA (strong recommendation; moderate-quality evidence), and mandibular advancement devices as an alternative therapy to CPAP for patients diagnosed with OSA who prefer mandibular advancement devices or for those with adverse events associated with CPAP (weak recommendation, low-quality evidence).

American Academy of Craniofacial Pain

The American Academy of Craniofacial Pain (2013) published a position paper.⁴² It indicated that oral appliance therapy was recognized as an effective therapy for many with primary snoring and mild-to-moderate OSA, as well as those with more severe OSA who cannot tolerate PAP therapies, but that oral appliance therapy has the potential to cause adverse events, including temporomandibular joint pain and dysfunction. The Academy recommended that dentists engaged in, or who want to engage in, the assessment and management of patients with snoring and OSA using mandibular advancement OA be properly trained and experienced in the assessment, diagnosis, and management of temporomandibular joint and craniofacial pain.

American Society of Metabolic and Bariatric Surgery

The American Society of Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA (reviewed in October 2015).⁴³ The guidelines noted that while some reports in the literature have recommended routine screening for OSA prior to bariatric surgery, other reports have suggested clinical screening only does not result in any increase in postoperative pulmonary complications after laparoscopic Roux-en-Y gastric bypass, and that most current surgical practices refer patients with clinical symptoms of OSA for PSG, but do not make this a routine preoperative test prior to bariatric surgery. The Society provided, based on the evidence in the literature to date, the following guidelines on OSA in the bariatric surgery patient and its perioperative management:

1. "OSA is highly prevalent in the bariatric patient population...."

4. [Patients with moderate to severe OSA] should bring their CPAP machines, or at least their masks, with them at the time of surgery and use them following bariatric surgery at the discretion of the surgeon.

7. Routine pulse oximetry or capnography for postoperative monitoring of patients with OSA after bariatric surgery should be utilized, but the majority of these patients do not routinely require an ICU [intensive care unit] setting.

8. No clear guidelines exist upon which to base recommendations for retesting for OSA following bariatric surgery...."

American Academy of Otolaryngology-Head and Neck Surgery

The American Academy of Otolaryngology-Head and Neck Surgery (2011) published guidelines on PSG for sleep-disordered breathing prior to tonsillectomy in children, which included the following⁴⁴:

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

American Thoracic Society

The American Thoracic Society (2016) published a statement on the long-term effects and treatment of mild OSA in adults.⁴⁵ The Society's systematic review concluded:

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

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2017) reported on the evidence for screening for OSA in adults and concluded that "the current evidence is insufficient to assess the balance and harms of screening for obstructive sleep apnea (OSA) in asymptomatic adults. Evidence on screening tools to accurately detect persons in asymptomatic populations who should receive further testing and treatment of subsequently diagnosed OSA to improve health outcomes is lacking, and the balance of benefits and harms cannot be determined."^{46,47}

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in May 2020 identified over 300 studies on diagnosis and medical management of OSA.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

94660	Continuous positive airway pressure ventilation (CPAP), initiation and management
94762	Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)
95782	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone), and sleep time
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95806	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808	Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811	Polysomnography; ; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist
A7002	Tubing, used with suction pump, each
A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each
A7028	Oral cushion for combination oral/nasal mask, replacement only, each
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair
A7030	Full face mask used with positive airway pressure device, each
A7031	Face mask interface, replacement for full face mask, each
A7032	Cushion for use on nasal mask interface, replacement only, each
A7033	Pillow for use on nasal cannula type interface, replacement only, pair
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
A7035	Headgear used with positive airway pressure device
A7036	Chinstrap used with positive airway pressure device
A7037	Tubing used with positive airway pressure device

A7038	Filter, disposable, used with positive airway pressure device
A7039	Filter, non-disposable, used with positive airway pressure device
A7044	Oral interface used with positive airway pressure device, each
A7045	Exhalation port with or without swivel used with accessories for positive airway devices, replacement only
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment
E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous airway pressure (CPAP) device
E1399	Durable medical equipment, miscellaneous
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels
K1027	“Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment Effective 10-01-2021

Attended Studies

- CPT Codes: 95807, 95808, 95810, 95811, 95782, 95783.

Unattended Study

- CPT Codes: 95806 (Note that this CPT code is identical to 95807 except that the study is not monitored.) 95800, 95801 (These differ from 95806 in the description of a single respiratory sensor [either air flow or peripheral arterial tone] instead of the standard configuration of both respiratory effort and respiratory airflow [ventilation]).
- Use of overnight oximetry alone would be indicated by CPT code 94762.

HCPCS Codes

- There is 1 HCPCS code identifying a CPAP device, E0601, and 2 HCPCS codes for BiPAP devices: E0470 and E0471. The HCPCS codes do not distinguish among fixed CPAP or BiPAP devices and auto-adjusting CPAP devices.
- In 2008, Medicare created G codes to facilitate their national coverage decision: G0398, G0399, G0400.

- There is a HCPCS code for the oral interface used with devices such as the Winx system: A7047. The system would be reported using code E0600 (Respiratory Suction Pump, Home Model, Portable or Stationary, Electric) and code A7002 (Tubing, Used with Suction Pump, Each).

DIAGNOSES

These diagnoses are otherwise subject to medical policy as stated above.

ICD-10 Diagnoses

- G47.10 Hypersomnia, unspecified
- G47.11 Idiopathic hypersomnia with long sleep time
- G47.12 Idiopathic hypersomnia without long sleep time
- G47.13 Recurrent hypersomnia
- G47.30 Sleep apnea, unspecified
- G47.31 Primary central sleep apnea
- G47.33 Obstructive sleep apnea (adult) (pediatric)
- G47.35 Congenital central alveolar hypoventilation syndrome
- G47.39 Other sleep apnea
- G47.411 Narcolepsy with cataplexy
- G47.419 Narcolepsy without cataplexy
- G47.421 Narcolepsy in conditions classified elsewhere with cataplexy
- G47.429 Narcolepsy in conditions classified elsewhere without cataplexy
- G47.8 Other sleep disorders
- G47.9 Sleep disorder, unspecified
- R06.81 Apnea, not elsewhere classified
- R40.0 Somnolence

REVISIONS	
01-01-2011	<p>In Title:</p> <ul style="list-style-type: none"> ▪ Policy title changed from "Polysomnography and Sleep Studies" to "Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome"
	<p>Description section updated</p>
	<p>In policy section:</p> <ul style="list-style-type: none"> ▪ Revised wording to current medical policy wording from: "BCBSKS encourages sleep study facilities to become accredited through the American Academy of Sleep Medicine (AASM) and/or the Accreditation Commission for Health Care, Inc. (ACHC) and physicians to be board certified in sleep medicine. The following criteria and documentation for medical necessity applies to all providers, regardless of their accreditation or certification level. Polysomnography is indicated: <ul style="list-style-type: none"> ▪ for diagnosis of sleep related breathing disorders, ▪ for continuous positive airway pressure (CPAP) titration in patient's sleep related breathing disorders, ▪ for documenting the presence of obstructive sleep apnea for patients prior to surgical interventions, ▪ for the assessment of treatment results in some cases, ▪ with a multiple sleep latency test in the evaluation of suspected narcolepsy, ▪ in evaluating sleep related behaviors that are injurious, and ▪ in certain atypical or unusual parasomnias Medically necessary indications for polysomnography for adults include one or more of the following:

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	<ol style="list-style-type: none"> 1. Witnessed apnea during sleep; OR 2. Any combination of two or more of the following (a through d): <ol style="list-style-type: none"> a. Excessive daytime sleepiness as evidenced by one or more of the following: <ul style="list-style-type: none"> ▪ Inappropriate daytime napping (e.g., during driving, conversation, or eating); ▪ Sleepiness that interferes with daily activities; (The following should be ruled out as a cause for these symptoms: poor sleep hygiene, medication, drugs, alcohol, hypothyroidism, other medical diagnoses, psychiatric, or psychological disorders, social or work schedule changes.) ▪ An Epworth Sleepiness Scale score greater than 10; or b. Persistent or frequent socially disruptive snoring; or c. Obesity (BMI greater than 30 kg/m²) or hypertension; or d. Choking or gasping episodes associated with awakening. OR 3. Symptoms suggesting narcolepsy, e.g., sleep paralysis, hypnagogic hallucinations, cataplexy; OR 4. Violent or injurious behavior during sleep; OR 5. Other situations (if nocturnal pulse oximetry suggests nocturnal oxygen desaturation) such as <ul style="list-style-type: none"> ▪ Unexplained right heart failure; ▪ Unexplained polycythemia; ▪ Presence of or increase in cardiac arrhythmias during sleep; ▪ Unexplained pulmonary hypertension. OR 6. Excessive daytime sleepiness together with witnessed periodic limb movements of sleep; OR 7. Unusual or atypical parasomnias based on patient's age, frequency, or duration of behavior; OR 8. Patients with moderate or severe congestive heart failure, stroke/TIA, coronary artery disease, or significant tachycardic or bradycardic arrhythmias who have nocturnal symptoms suggestive of a sleep related breathing disorder or otherwise suspected of having sleep apnea. <p>Repeat standard polysomnography for adults is considered medically necessary under the following circumstances:</p> <ol style="list-style-type: none"> 1. Failure of resolution of symptoms or recurrence of symptoms during treatment; OR 2. Post-operatively following uvulopalatopharyngoplasty (UPPP) or other corrective surgeries for obstructive sleep apnea (due to the variable outcome of these surgical procedures); OR 3. Following treatment with an oral appliance for obstructive sleep apnea with an apnea hypopnea index (an AHI) or respiratory disturbance index (RDI) of >15 pre-treatment to ensure effective treatment; OR 4. To titrate CPAP following an initial polysomnography where obstructive sleep apnea was demonstrated and a split night study was not feasible; OR 5. To reevaluate the diagnosis of obstructive sleep apnea and need for continued CPAP in a patient previously diagnosed by polysomnography and currently using CPAP, if a significant weight loss has occurred since the initial study. <p>Not Medically Necessary: <u>Two Separate Night Studies</u> Two separate nights' polysomnography studies, one for the diagnosis of sleep disorders and the second to titrate CPAP, are generally considered not medically necessary unless circumstances do not allow for half night or "split night" polysomnography with titration of CPAP performed in the second part of the study, (e.g., significant obstructive sleep apnea, [that is with an AHI or RDI of 20 or more with oxygen desaturations], not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM</p>

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	<p>sleep). In these cases, a second full night’s study may then be medically necessary for CPAP titration.</p> <p><u>Repeat Standard Polysomnography</u></p> <p>Repeat polysomnography is considered not medically necessary in the follow-up of patients with obstructive sleep apnea treated with CPAP when symptoms attributable to sleep apnea have resolved.</p> <p>Polysomnography is not routinely indicated:</p> <ul style="list-style-type: none"> ▪ to diagnose or treat restless legs syndrome, ▪ for the diagnosis of circadian rhythm sleep disorders, ▪ to establish a diagnosis of depression, ▪ for the following conditions existing alone in the absence of other features suggestive of obstructive sleep apnea: Snoring, obesity, hypertension, morning headaches, decrease in intellectual functions, memory loss, frequent nighttime awakenings, other sleep disturbances, such as insomnia (acute or chronic), night terrors, sleep walking, epilepsy where nocturnal seizures are not suspected, common uncomplicated non-injurious parasomnias <p>Unattended (unsupervised) sleep studies are considered experimental / investigational.</p> <p>DOCUMENTATION</p> <p>Prior to performing a sleep study, the sleep laboratory’s Medical Director or physician should ascertain that the following have been completed and establish the medical necessity of the test. It is expected that the sleep laboratory will either assess the information from the ordering physician or acquire the information and document it so that medical necessity is well established or indicate why an exception is valid. Either ordering physician or sleep lab physician must sign off that these steps have been documented and evaluated prior to sleep study. This information should be kept on file for medical necessity reviews and audit purposes.</p> <ol style="list-style-type: none"> 1. History and physical/sleep related symptoms, significant medical conditions, medical findings, medications, allergies, and personal habits that could affect the sleep status (i.e., alcohol consumption, psychiatric condition) should be included. Such things as a two week sleep diary may have been completed. An assessment should be made and signed by the ordering physician, and must be reviewed by the sleep laboratory or obtained by the sleep laboratory physician, in order to establish the appropriate testing and medical necessity. The history should also document an effort to screen for the possibility of depression. 2. A sleep evaluation questionnaire (mini survey), such as the Berlin questionnaire, should have been completed and assessed by the ordering physician and/or the sleep laboratory (standard questionnaire if information is not included in #1 above). 3. A sleepiness scale, such as an Epworth scale, should have been completed. Once again, the sleep laboratory is to ascertain that the sleepiness scale fits with a clinical picture that would establish medical necessity. 4. There is an expectation that potential therapeutic options have been discussed thoroughly with the patient and potential compliance issues have been addressed. This should have been done by the ordering physician or by the sleep laboratory physician. It is also the expectation that the sleep laboratory will determine the individual education needs of the patient and will provide this education (i.e., CPAP therapy).” <ul style="list-style-type: none"> ▪ Policy Guidelines added
	Rationale section added
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Removed CPT Codes: 0203T, 0204T ▪ Added CPT Codes: 94660, 94762, 95800, 95801

REVISIONS	
	<ul style="list-style-type: none"> ▪ Added HCPCS Codes: A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, E0470, E0471, E0485, E0486, E0561, E0562, E0601 ▪ Removed Diagnosis Codes: 327.24, 327.27, 770.81, 780.09, 780.52, 780.55, 780.56 ▪ Added Diagnosis Codes: 327.10, 327.11, 327.13, 327.29 ▪ Correct 347 to reflect: 347.00, 347.01, 347.10, 347.11 <p>References section updated</p>
01-12-2011	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Removed from II B 2 the following wording as it was erroneously listed in the pediatric section of the policy, "(e.g., significant obstructive sleep apnea, [that is with an AHI or RDI of 20 or more with oxygen desaturations], not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep)."
02-25-2011	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Removed the word "Titration" from I. B. and II. B. entitled CPAP Titration to read "CPAP". ▪ Corrected an error in Policy Guidelines #1, by removing "and an associated fall in oxygen saturation of at least 4%." from the sentence "An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort and an associated fall in oxygen saturation of at least 4%." to read "An obstructive apnea is defined as at least a 10-second cessation of respiration associated with ongoing ventilatory effort." ▪ Corrected an error in Policy Guidelines #1 by changing "...4% oxygen desaturation." to "...3% oxygen desaturation."
08-30-2012	<p>Description section updated</p> <p>In Policy section:</p> <ul style="list-style-type: none"> ▪ Revised policy sections from "I. Adults – 18 and over" and "II. Children – under 18" to "I. Diagnosis" and "II. Medical Management" and reformatted the indications to fall under each respectively. ▪ In I A 1 b c) added "(this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children)" to read "sleepiness that interferes with daily activities and is not explained by other conditions (this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children)" ▪ In I A 1 b 4) added "or greater than the 90th percentile for the weight/height ratio in pediatric patients," to read "Obesity, defined as a body mass index greater than 30 kg/m² in adults or greater than the 90th percentile for the weight/height ratio in pediatric patients," ▪ Moved the pediatric supervised polysomnography indications from the prior Pediatric section to become I A 1 i under the new Diagnosis section (no change in indications) ▪ In I B 1 c added "severe" to the unattended (unsupervised) Home Sleep Studies indication of chronic pulmonary disease to read, "Severe chronic pulmonary disease" ▪ In I B 2 added "and in pediatric patients" to read, "Unattended (unsupervised) sleep studies are considered experimental / investigational in adult patients who are considered at low to moderate risk for OSA and in pediatric patients." ▪ In I C Repeat Supervised Polysomnography added, <ul style="list-style-type: none"> "1. To initiate and titrate continuous positive airway pressure (CPAP) in adult patients with clinically significant OSA defined as those patients who have: <ul style="list-style-type: none"> a. An apnea/hypopnea index (AHI) of at least 15 per hour, OR b. An AHI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension. <p>Note:</p> <ul style="list-style-type: none"> ▪ In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 is considered severe.

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	<ul style="list-style-type: none"> ▪ A split-night study, in which severe OSA is documented during the first portion of the study using polysomnography, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines for criteria to perform a split-night study)." ▪ Removed from I E "[that is with an AHI or RDI of 20 or more with oxygen desaturations]," to read "e.g., significant obstructive sleep apnea, [that is with an AHI or RDI of 20 or more with oxygen desaturations], not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep)." ▪ Added the new medically necessary indication of "II B Bilevel positive airway pressure or auto-adjusting CPAP may be considered medically necessary in patients with clinically significant OSA AND who have failed a prior trial of CPAP or for whom BiPAP is found to be more effective in the sleep lab." ▪ Revised Intraoral Appliances from "Intraoral appliances* may be considered medically necessary in patients with clinically significant OSA, as defined in Policy Guidelines. *Intraoral appliances include either tongue-retaining devices or mandibular advancing/positioning devices." to "Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in patients with clinically significant OSA under the following conditions: <ol style="list-style-type: none"> 1. OSA, defined by an apnea/hypopnea index (AHI) of at least 15 per hour or an AHI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension, AND 2. The device is prescribed by a treating physician, AND 3. The device is custom-fitted by qualified dental personnel. AND Note: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for patients with severe OSA, as oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-moderate OSA. Therefore, it is particularly important that patients with severe OSA should 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." ▪ Added the new experimental / investigational indication of "A nasal expiratory positive airway pressure (EPAP) device is considered experimental / investigational." ▪ Policy Guidelines updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> ▪ Add HCPCS Code: E1399
	References updated
01-01-2013	In Coding section: <ul style="list-style-type: none"> ▪ Added CPT codes: 95782, 95783 (effective 01-01-2013) ▪ Revised nomenclature on CPT code: 95808, 95810, 95811 (effective 01-01-2013)
09-16-2015	Description section updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> • HCPCS Code Removed: E1399 • Coding instructional information updated. • ICD-10 Codes added.
	References updated
01-01-2020	Policy published 12-02-2019. Policy effective 01-01-2020.
	Description section updated
	In Policy section: <table border="1" style="width: 100%;"> <tr> <td>Policy changes in summary are: Diagnosis-Home Sleep Apnea Test</td> </tr> </table>
Policy changes in summary are: Diagnosis-Home Sleep Apnea Test	

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- include new terminology of home sleep apnea test versus home sleep studies
 - revising health conditions when home sleep apnea test is not eligible
 - clarify that devices include a minimum of 3 sensors
 - add medical necessity for unattended home sleep apnea test as a screening tool in patient who are scheduled for bariatric surgery when criteria are met
- Diagnosis-Supervised Polysomnography
- revised eligibility criteria to when home sleep apnea test criteria is not met
 - revised presence of comorbidity eligibility
 - re-defined AHI, RDI, and REI criteria
 - removed Two Separate Night Studies criteria
 - added PAP-NAP E/I statement
- Medical Management
- added auto-adjusting medical necessity and criteria
 - updated intraoral appliances criteria
 - added palate, mandible expansion and oral pressure therapy devices E/I statements

Policy changed to the current policy from the following:

"I. Diagnosis

A. Supervised Polysomnography

1. Supervised polysomnography performed in a sleep laboratory may be considered medically necessary as a diagnostic test in patients with any of the following:
 - a. Observed apneas during sleep OR
 - b. A combination of at least 2 of the following:
 - 1) Excessive daytime sleepiness evidenced by:
 - a) an Epworth Sleepiness Scale greater than 10
 - 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 (this may be expressed as learning difficulties or other daytime neurobehavioral problems in young children)
 - 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/m² in adults or greater than the 90th percentile for the weight/height ratio in pediatric patients,
 - 5) Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy,
 - 6) Neuromuscular disease OR
 - c. Moderate or severe congestive heart failure, stroke/transient ischemic attack, coronary artery disease, or significant tachycardia or bradycardic arrhythmias in patients who have nocturnal symptoms suggestive of a sleep-related breathing disorder or otherwise are suspected of having sleep apnea OR
 - d. Symptoms suggesting narcolepsy, e.g., sleep paralysis, hypnagogic hallucinations, cataplexy OR
 - e. Violent or injurious behavior during sleep OR
 - f. Other situations (if nocturnal pulse oximetry suggests nocturnal oxygen desaturation) such as:
 - 1) Unexplained right heart failure
 - 2) Unexplained polycythemia
 - 3) Presence of or increase in cardiac arrhythmias during sleep
 - 4) Unexplained pulmonary hypertension OR
 - g. Excessive daytime sleepiness together with witnessed periodic limb movements of sleep OR
 - h. Unusual or atypical parasomnias based on patient's age, frequency, or duration of behavior OR
 - i. Pediatrics— under 18 – with ANY of the following additional indications:
 - 1) behavioral problems, which may be expressed as:
 - a) learning difficulties OR
 - b) daytime neurobehavioral problems in young children OR
 - 2) hyperactivity OR
 - 3) snoring alone OR
 - 4) chronic disturbed sleep

Risk factors include:

 - adenotonsillar hypertrophy
 - obesity (defined as greater than the 90th percentile for the weight/height ratio)
 - craniofacial anomalies, and
 - neuromuscular disorders
2. Routine supervised polysomnography is not medically necessary for the following:
 - a. To diagnose or treat restless legs syndrome

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	<ul style="list-style-type: none"> b. To establish a diagnosis of depression c. For the following conditions existing alone in the absence of other features suggestive of obstructive sleep apnea: <ul style="list-style-type: none"> 1) Snoring 2) Obesity 3) Hypertension 4) Morning headaches 5) Decrease in intellectual functions 6) Memory loss 7) Frequent nighttime awakenings 8) Other sleep disturbances, such as insomnia (acute or chronic), night terrors, sleep walking, epilepsy where nocturnal seizures are not suspected 9) Common uncomplicated non-injurious parasomnias <p>B. Unattended (unsupervised) Home Sleep Studies</p> <ul style="list-style-type: none"> 1. Unattended (unsupervised) home sleep studies with a minimum of 4 recording channels (2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation) may be considered medically necessary in adult patients who are at risk for OSA and have no evidence by history or physical examination of a health condition that might alter ventilation or require alternative treatment, including the following: <ul style="list-style-type: none"> a. Central sleep apnea b. Congestive heart failure c. Severe chronic pulmonary disease d. Obesity hypoventilation syndrome e. Narcolepsy f. Periodic limb movements in sleep g. Restless leg syndrome Note: Respiratory disturbance index may be used in place of apnea/hypopnea index (AHI) in unattended sleep studies. 2. Unattended (unsupervised) sleep studies are considered experimental / investigational in pediatric patients. <p>C. Repeat Supervised Polysomnography</p> <p>A repeat supervised polysomnography performed in a sleep laboratory may be considered medically necessary under the following circumstances:</p> <ul style="list-style-type: none"> 1. To initiate and titrate continuous positive airway pressure (CPAP) in adult patients with clinically significant OSA defined as those patients who have: <ul style="list-style-type: none"> a. An apnea/hypopnea index (AHI) of at least 15 per hour, OR b. An AHI of at least 5 per hour in a patient with excessive daytime sleepiness or unexplained hypertension. Note: <ul style="list-style-type: none"> ▪ In pediatric patients, an AHI greater than 1.5 is considered abnormal, and an AHI of 15 is considered severe. ▪ A split-night study, in which severe OSA is documented during the first portion of the study using polysomnography, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines for criteria to perform a split-night study). OR 2. Failure of resolution of symptoms or recurrence of symptoms during treatment OR 3. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices OR 4. 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 Note: This statement does not imply that supervised studies are needed routinely following unattended studies. This statement means a re-evaluation based on a substantial change in symptoms or in the clinical situation. <p>D. Repeat Unattended (unsupervised) Home Sleep Studies</p> <p>Repeat unattended (unsupervised) home sleep studies with a minimum of four recording channels (2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation) may be considered medically necessary in adult patients under the following circumstances:</p> <ul style="list-style-type: none"> 1. To assess efficacy of surgery or oral appliances/devices; OR 2. 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. <p>E. Two Separate Night Studies</p> <p>Two separate nights' polysomnography studies, one for the diagnosis of sleep disorders and the second to titrate CPAP, are generally considered not medically necessary unless circumstances do not allow for half night or "split night" polysomnography with titration of CPAP performed in the second part of the</p>

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	<p>study, (e.g., significant obstructive sleep apnea not identified in time to allow for at least 3 hours of CPAP titration including both REM and non-REM sleep). In these cases, a second full night's study may then be medically necessary for CPAP titration.</p> <p>F. Multiple Sleep Latency Testing Multiple sleep latency testing is considered not medically necessary in the diagnosis of OSA except to exclude or confirm narcolepsy in the diagnostic workup of OSA syndrome.</p> <p>II. Medical Management</p> <p>A. CPAP CPAP may be considered medically necessary in adult patients with clinically significant OSA defined as:</p> <ol style="list-style-type: none"> 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 or insomnia, or documented hypertension, ischemic heart disease, or history of stroke, OR 3. For pediatric patients: <ol style="list-style-type: none"> a. AHI or RDI of at least 5 per hour, or b. AHI or RDI of at least 1.5 per hour in a patient with excessive daytime sleepiness, behavioral problems or hyperactivity. <p>Note: AHI greater than 1.5 is considered abnormal, and AHI of 15 or more is considered severe.</p> <p>B. Bilevel positive airway pressure or auto-adjusting CPAP may be considered medically necessary in patients with clinically significant OSA AND who have failed a prior trial of CPAP or for whom BiPAP is found to be more effective in the sleep lab.</p> <p>C. Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in patients with clinically significant OSA under the following conditions: <ol style="list-style-type: none"> 1. OSA, defined by an apnea/hypopnea index (AHI) of at least 15 per hour or an AHI of at least 5 events per hour in a patient with excessive daytime sleepiness or unexplained hypertension AND 2. The device is prescribed by a treating physician AND 3. The device is custom-fitted by qualified dental personnel. <p>Note: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for patients with severe OSA, as oral appliances have been shown to be less efficacious in patients with severe OSA than they are in patients with mild-moderate OSA. Therefore, it is particularly important that patients with severe OSA should 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.</p> </p> <p>D. A nasal expiratory positive airway pressure (EPAP) device is considered experimental / investigational.</p>
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> ▪ Added CPT Code: A7002 ▪ Added ICD-10 Codes: G47.8, G47.9, R06.81
	References updated
04-16-2021	Description section updated
	Rationale section updated
	References updated
06-21-2021	<p>The following changes were made to the Policy section based on recommendations from the Dental Advisory Committee.</p> <p>Item II.D.4</p> <ul style="list-style-type: none"> • Added "a dentist or by" and "under the supervision of a dentist" <p>Item II.D.5</p> <ul style="list-style-type: none"> • Replaced "There is absence of temporomandibular dysfunction or periodontal disease" with "The patient has been cleared by a dentist"
10-01-2021	In Coding section Added HCPCS code: K1027 Effective 10-01-2021

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