

2.01.18	Diagnosis of Obstructive Sleep Apnea Syndrome		
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Section:	2.0 Medicine	Page:	Page 1 of 28

Policy Statement

Blue Shield of California (BSC) requires an unattended (unsupervised) home sleep apnea test ([HSAT](#)) as the initial study for the screening for and diagnosis of *moderate to severe* obstructive sleep apnea (OSA) in adults unless contraindicated.

Prior authorization is not required for HSATs. However, treatment based on HSAT results will not be approved unless the following criteria are met:

- I. Documentation that the device used meets **either** of the following criteria:
 - A. **All** of the following sensors:
 1. Nasal pressure
 2. Chest and abdominal respiratory inductance plethysmography
 3. Oximetry; OR
 - B. Utilization of Peripheral Arterial Tone (PAT) with oximetry and actigraphy
- II. The individual is at least 18 years old
- III. There are no contraindications to a home sleep study

Note: Although the technologies noted in I.A and B are recommended, the following technologies are acceptable in place of I.A.2. above when nasal pressure and oximetry are also used:

1. Single thoracoabdominal RIP belt
 2. Single or dual thoracoabdominal polyvinylidene fluoride ([PVDF](#)) belts
 3. Single or dual thoracoabdominal piezo belts
 4. Single or dual pneumatic belts
- I. Repeat unattended (unsupervised) home sleep apnea test with a minimum of recording channels as described above may be considered **medically necessary** in adults under **any** of the following circumstances:
 - A. To assess efficacy of surgery or oral appliances or devices
 - B. To reevaluate the diagnosis of OSA and need for continuous positive airway pressure (CPAP) (e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued)
 - C. As a screening tool for individuals who are planning for bariatric surgery and have no evidence of a contraindication to a HSAT
 - II. Unattended home sleep studies are considered **investigational** in children (less than 18 years of age).
 - III. Repeat unattended HSATs are considered **investigational** when done routinely on sequential nights or within a short time period to make or confirm a diagnosis of OSA or to further evaluate OSA when there are no technical problems that would necessitate a repeat test.

Supervised Polysomnography (PSG) in a Sleep Laboratory

Note: A split-night study, in which moderate-to-severe OSA is documented during the first portion of the study using PSG, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP and should be done when appropriate unless documentation is provided why it cannot or was not done.

- IV. An initial supervised polysomnography (PSG) performed in a [sleep laboratory](#) may be considered **medically necessary** for an individual with a moderate or high pretest probability of OSA in **any** of the following situations:
- A. A previous home study failed to establish the diagnosis of OSA in an individual with a high pretest probability of OSA
 - B. A previous home study was [technically inadequate](#)
 - C. Failure of resolution of symptoms or recurrence of symptoms during treatment
 - D. When testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy (see Blue Shield of California Medical Policy: Polysomnography for Non-Respiratory Sleep Disorders)
 - E. Presence of a known comorbidity (a [contraindication](#) to HSAT; see [Policy Guidelines](#) section) that might alter ventilation or decrease the accuracy of a home sleep apnea test
 - F. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA
 - G. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed
 - H. Pediatric individual (i.e., less than 18 years of age)
- V. An initial supervised polysomnography (PSG) performed in a sleep laboratory may be considered **medically necessary** for an individual after OSA has been treated or ruled out by a HSAT, when testing is done to look for other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy (a PSG is often done immediately prior to multiple sleep latency testing even when OSA is not a concern)
- VI. A repeat, supervised polysomnography (PSG) performed in a [sleep laboratory](#) may be considered **medically necessary** for an individual with a moderate or high pretest probability of OSA in **any** of the following situations:
- A. To initiate and titrate CPAP for an adult patient who has [clinically significant OSA](#)
 - B. Failure of resolution of symptoms or recurrence of symptoms during treatment
 - C. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA
 - D. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed
 - E. To assess efficacy of adenotonsillectomy for a patient under the age of 18
 - F. To initiate and titrate CPAP for a child with **either** of the following:
 - 1. An AHI or RDI of greater than or equal to 5 events per hour
 - 2. An AHI or RDI greater than or equal to 1.5 events per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity
- VII. Auto-adjusting positive airway pressure (APAP) may be considered **medically necessary** for the titration of pressure as an alternative to a CPAP titration PSG or CPAP use in adults with [clinically significant OSA](#).
- VIII. Supervised or unattended home sleep apnea tests that do not meet the above criteria are considered **investigational**.
- IX. Multiple sleep latency testing is considered **investigational** in the diagnosis of OSA.

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Home Sleep Apnea Test Devices

American Academy of Sleep Medicine (AASM) updated their guidelines in 2019 to recommend devices using BOTH a respiratory and abdominal belt (dual belt). Heart rate is no longer required. In addition, devices using PAT technology (e.g., WatchPAT) are also recommended. However, some other devices are considered to be acceptable, including some with single belts and some using different technology (using CPT 95806). The WatchPAT device uses CPT code 95800, and is now allowed as an acceptable device choice.

New devices using dual respiratory effort belts (chest and abdomen) should use CPT code G0400 since there is no heart rate. Code 95801 should not be used since it does not have the required types of channels.

Oximetry may be noted by the terms pulse oximetry (SpO₂), oxygen saturation or CO-oximetry (measures carbon monoxide [CO] in addition to oxygen saturation).

Piezoelectricity is Greek for "pressure" electricity.

PVDF film used in respiratory effort belts produces a signal when subjected to acceleration or force. Unlike RIP belts, PVDF belts do not require an external power source. The PVDF film generates its own charge when force or acceleration is applied. A small DC battery is used to convert that signal for PSG.

A technically adequate diagnostic test includes a minimum of 4 hours of technically adequate oximetry and flow data, obtained during a recording attempt that encompasses the habitual sleep period.

BSC approval for all OSA therapeutic devices (including CPAP, APAP, bilevel positive airway pressure [BiPAP] and oral appliances) is based on the acceptable performance of an initial sleep apnea diagnostic test.

Contraindications to HSAT

Contraindications to home sleep studies include, but are not limited to significant, ongoing symptoms related to:

- Central sleep apnea
- Heart failure
- Chronic pulmonary disease
- Obesity hypoventilation syndrome
- Neuromuscular disorders with sleep-related symptoms
- Stroke or recurrent Transient Ischemic Attacks (TIAs)
- Coronary Artery Disease
- Tachycardic or bradycardic arrhythmias
- Injurious or potentially injurious parasomnias
- Narcolepsy

Sleep Lab Test

If the request for CPT code 95810 is approved and the sleep study meets Blue Shield of California (BSC) Medical Policy requirements for a split night sleep study with CPAP titration during the study, please submit the claim for CPT code 95811 instead of CPT code 95810. Separate prior authorization for 95811 is not needed under these circumstances.

Definition of 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.

The following are generally accepted measures of OSA severity in adults:

- **None/minimal:** AHI, RDI, or REI less than 5 events/hour
- **Mild:** AHI, RDI, or REI greater than or equal to 5 events/hour but less than 15 events/hour
- **Moderate:** AHI, RDI, or REI greater than or equal to 15 events/hour but less than 30 events/hour
- **Severe:** AHI, RDI, or REI greater than or equal to 30 events/hour

Clinically Significant OSA in an adult

Includes either of the following:

- An Apnea/Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), or Respiratory Event Index (REI) of at least 15 events per hour
- An AHI, RDI, or REI of at least 5 events per hour in a patient with excessive daytime sleepiness (as determined by standard sleep questionnaires such as the Epworth Sleepiness Scale >10 or the Berlin Questionnaire with a score of at least 2 in Category 2) or hypertension

Auto-adjusting positive airway pressure (APAP) may be considered medically necessary for the titration of pressure in adults with clinically significant OSA.

Hypertension

Systolic BP \geq 140 or diastolic BP \geq 90, or on current medical treatment for hypertension.

Risk Factors for Obstructive Sleep Apnea

Although not an exclusive list, individuals with any two of the following symptoms are considered to have a moderate-to-high probability for moderate to severe 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 (e.g., age of the patient, male gender, thick neck, craniofacial or upper airway soft tissue abnormalities, or hypertension) may be considered. Objective clinical prediction rules are being developed; at present, risk assessment is based primarily on clinical judgment.

Other risk factors for OSA include the following:

- Abrupt awakenings accompanied by gasping or choking
- Awakening with a dry mouth or sore throat
- Morning headache
- Impaired daytime concentration
- Mood volatility
- Nocturnal diaphoresis
- Decreased libido
- Enlarged neck size: males: 16.5 inches (43 cm); females: 15 inches (38 cm)
- Mallampati 4 classification

Obesity-Hypoventilation Syndrome

Defined as daytime alveolar hypoventilation (awake arterial $P_{CO_2} > 45$ mm Hg or serum bicarbonate ≥ 27) among patients with body mass index ≥ 30 kg/m² in the absence of other causes of hypoventilation.

Neuromuscular Diseases Contraindicating Home Sleep Studies

- Amyotrophic lateral sclerosis (ALS)
- Charcot-Marie-Tooth disease
- Multiple sclerosis
- Muscular dystrophy
- Myasthenia gravis
- Myopathy, severe
- Myositis, including polymyositis and dermatomyositis
- Peripheral neuropathy, severe
- Spinal muscular atrophy

Sleep Questionnaires

The following sleep questionnaires (all self-answered by the patient) attempt to quantify the probability of having OSA:

- Epworth Sleepiness Scale: Comprised of eight questions with a maximum score of 24. A score of greater than 10 indicates moderate to high probability of OSA.
- Berlin Questionnaire: Comprised of 10 questions and three scoring categories. Two or more positive categories indicate a high probability of OSA.
- STOP-BANG: Comprised of eight questions. A "yes" answer on three or more questions indicates a high probability of OSA. The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (**S**nore, **T**ired, **O**bserved apnea, **B**lood **P**ressure, **B**MI, **A**ge, **N**eck, **G**ender) and has been shown to have 97% sensitivity and a negative predictive value of 96% (specificity of 33%) for the identification of individuals with severe OSA (Apnea/Hypopnea Index [AHI] score greater than 30 events per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is inadequate for the diagnosis of OSA. Therefore, a follow-up polysomnography (PSG) or home sleep apnea test would still be required to confirm or exclude a diagnosis of OSA.

Obstructive Sleep Apnea in Children

The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a BMI greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI or RDI greater than 1.5 events per hour is considered abnormal (an AHI or RDI greater than or equal to 10 events per hour may be considered severe).

Bariatric Surgery

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

Significant Weight Change

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

**Multiple Sleep Latency Test

The multiple sleep latency test (MSLT) is an objective measure of the tendency to fall asleep in the absence of alerting factors, while the maintenance of wakefulness test is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). The MSLT and maintenance of wakefulness test are not routinely indicated in the evaluation and diagnosis of OSA or in the assessment of change following treatment with continuous positive airway pressure (CPAP). The MSLT may be indicated in the evaluation of individuals 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 or ruled out before confirming a diagnosis of narcolepsy with the MSLT.

Specialist Training

Polysomnography (PSG) or home sleep apnea testing should be performed in appropriately selected individuals and the test summary results reviewed by a provider who is trained in sleep medicine. Medical professionals who interpret a polysomnogram or home sleep apnea test should be trained in sleep medicine and should review the raw data from PSG and home sleep apnea tests to detect artifacts and data loss.

Split-Night Studies

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

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

Note: A split-night study, in which moderate-to-severe OSA is documented during the first portion of the study using PSG, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP and should be done unless documentation is provided why it cannot or was not done.

Categorization of Polysomnography and Portable Monitoring

Full correspondence does not exist between CPT codes and the most current categorization scheme for the different types of studies. The 2005 practice parameters from the American Academy of Sleep Medicine list 4 types of monitoring procedures: type 1, standard attended in-lab comprehensive PSG; type 2, comprehensive portable PSG; type 3, modified portable sleep apnea testing (also referred to as cardiorespiratory sleep studies), consisting of 4 or more channels of monitoring; and type 4,

continuous single or dual bioparameters, consisting of 1 or 2 channels, typically oxygen saturation, or airflow. Types 1 and 2 would be considered polysomnographic studies, and types 3 and 4 would be considered polygraphic sleep studies. The terms sleep studies and PSG are often used interchangeably. CPT coding distinguishes between sleep studies that do not include electroencephalographic (EEG) monitoring, and PSG, which includes EEG monitoring. PSG is usually conducted in a sleep laboratory and attended by a technologist, but may also be conducted with type 2 portable monitoring. The type of study is further characterized as attended (supervised) or unattended by a technologist. Home or portable monitoring implies unattended sleep studies, typically conducted in the individual's home. There are no specific codes for remotely monitored home sleep studies. They would likely be reported with the CPT code for the sleep study with the GT modifier ("via interactive audio and video telecommunications systems") appended. There is no CPT code for "unattended" PSG.

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

Coding

The miscellaneous DME code E1399 is sometimes submitted as an extra charge for setup, training and instruction in the use of APAP. These services are included in payment for the device. They do not need to be addressed separately as they are covered by claims editing rules when a claim is made for payment.

Attended Studies

- **95807:** Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
- **95808:** Polysomnography; any age, 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
- **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

Unattended Studies

- **95800:** Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time
- **95801:** Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., by airflow or peripheral arterial tone)

- **95806:** Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement) (Note that this CPT code is identical to 95807 except that the study is not monitored)

95800 and 95801 differ from 95806 in the description of a single respiratory sensor (either air flow or peripheral arterial tone) instead of the configuration of both respiratory effort and respiratory airflow (ventilation). G0399 is similar to 95806. G0400 is best used for the new devices using 2 respiratory effort belts, oximetry and nasal pressure; however, it could also be used instead of 95801 (which does not meet criteria for approval). G0400 only states the need for at least 3 channels without specifying which ones, so review may be needed to determine which device is being requested for use.

Use of overnight oximetry alone would be indicated by the following CPT code:

- **94762:** Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)

HCPCS Codes

Medicare created the following G codes to facilitate their national coverage decision:

- **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

Refer to Blue Shield of California Medical Policy: Home Apnea Monitors for further information on neonatal home cardiorespiratory monitoring (CPT codes 94772-94777). These codes are not appropriate for the diagnosis of sleep apnea in children.

The following services are considered **inclusive** to the oral appliance: 21083, 70486, 70487, 76380, 97763, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, and 99215.

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.

Related Policies

- Actigraphy
- Home Cardiorespiratory Monitoring
- Medical Management of Obstructive Sleep Apnea Syndrome
- Polysomnography for Non-Respiratory Sleep Disorders

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract

language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

The SleepImage System for diagnosis of OSA is described in Table 1.

Table 1. Other Devices for OSA Diagnosis

Device	Manufacturer	Indications for Use	FDA Marketing Clearance	FDA Product Code	Year
<i>Diagnosis</i>					
SleepImage System	MyCardio	<p>The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality.</p> <p>The SleepImage System analyzes, displays and summarizes Electrocardiogram (ECG) or Plethysmogram (PLETH) data, typically collected during sleep, that is intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for children, adolescents and adults.</p> <p>The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing.</p> <p>The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.</p>	K182618	MNR	2019

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

Rationale

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 main risk factors for OSA include obesity, male sex, older age, large neck size, instability of the respiratory control system, and craniofacial dysmorphisms; additional factors include cardiovascular disease, diabetes, and metabolic syndrome. Since disorders linked to OSA are more common in ethnic minority groups, there are data supporting an increased risk of OSA in African Americans and American Indians.

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

Obstructive sleep apnea is widely underdiagnosed with up to 95% of individuals with clinically significant OSA reporting no prior OSA diagnosis. Moreover, underdiagnosis is particularly prevalent in Black patients. 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 (PSG) also typically includes electrocardiography and monitoring of respiratory airflow and 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 PSG for CPAP titration. Table 2 provides common respiratory events and respiratory event reporting terms and definitions.

Table 2. Definitions of Terms and Scoring Criteria for OSA

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

Terms	Definition
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	PAP may be CPAP or APAP or 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; bi-PAP: bi-level positive airway pressure; CPAP: continuous positive airway pressure; EEG: electroencephalogram; OSA: obstructive sleep apnea; PAP: positive airway pressure; RDI: Respiratory Disturbance Index; REI: Respiratory Event Index; RERA: respiratory event-related arousal; UARS: upper airway resistance syndrome.

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

Literature Review

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, 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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these

groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Multichannel Home Sleep Apnea Testing

Clinical Context and Test Purpose

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

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

Populations

The relevant population of interest is individuals with suspected OSA.

Interventions

The test being considered is home sleep apnea testing. Tests reviewed are multichannel home sleep testing.

Comparators

The established test for OSA is in-laboratory polysomnography (PSG). Laboratory PSG is a more complex procedure than home testing and is 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) (Table 3).

Table 3. Health Outcome Measures Relevant to OSA

Outcome	Measure	Description	Clinically Meaningful Difference (If Known)
Change in AHI	AHI	Mean change in AHI from baseline to posttreatment	Change from severe-to-moderate or mild OSA
AHI success	Percentage of patients achieving success	Studies may use different definitions of success, but the most common for AHI success is the Sher criteria	Sher criteria include a decrease in AHI of $\geq 50\%$ 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 likely they are to fall asleep in 8 different situations (eg, watching TV, sitting quietly in a car, or sitting and talking to someone)	An ESS of ≥ 10 is considered excessively sleepy. A decrease of 2 points is considered the MID. ³
FOSQ	30 questions	Disease-specific QOL 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 Scale; FOSQ: Functional Outcomes of Sleep Questionnaire; MID: minimal important difference; ODI: oxygen desaturation Index; OSA: obstructive sleep apnea; QOL: quality of life.

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

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

Study Selection Criteria

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

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

Review of Evidence

Systematic Reviews

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

Randomized Controlled Trials

Home sleep testing with 3 recording channels that include respiratory effort, airflow, and oxygen saturation, but not heart rate, are considered by some, including the Centers for Medicare & Medicaid, to be sufficient for home sleep 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.⁵ Included in the study were patients referred to tertiary hospitals in Spain for suspected OSA, who had snoring or sleep apneas observed by a partner, ESS score of 10 or greater, and absence of clinical suspicion of any other sleep pathology. Both groups of patients who were diagnosed with OSA received continuous positive airway pressure (CPAP) titration with a single auto-adjusting positive airway pressure (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 a 6-month follow-up. ESS score improved by -4.2 (95% confidence interval [CI], -4.8 to -3.6) in the home sleep testing group and by -4.9 (95% CI, -5.4 to -4.3) in the PSG group. With a noninferiority margin of 2 points on the ESS, home sleep testing was noninferior to in-laboratory PSG.

Section Summary: Multichannel Home Sleep Apnea Testing

Based on this evidence and society guidelines, portable monitoring with a minimum of 4 recording channels (including oxygen saturation, respiratory movements, airflow, an electrocardiogram or heart rate), or with a device that measures peripheral arterial tone (PAT), 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

Clinical Context and Test Purpose

The purpose of limited channel home sleep apnea tests in individuals with suspected OSA is to diagnose the condition and to inform a decision on appropriate treatment.

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

Populations

The relevant population of interest is individuals with suspected OSA.

Interventions

The test being considered is home sleep apnea testing. Tests reviewed are limited channel sleep testing (e.g., APAP, Apnea Risk Evaluation System).

Comparators

The established test for OSA is in-laboratory PSG. Laboratory PSG is a more complex procedure than home testing and is more limited in its availability. Other comparators include home sleep testing with at least 3 recording channels.

Outcomes

The general outcomes of interest are the number of apneas or hypopneas during sleep, measured by the AHI, and subjective symptoms of sleepiness, typically measured with the ESS or the FOSQ, as described in Table 3, above.

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

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

Study Selection Criteria

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

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

Review of Evidence

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

Randomized Controlled Trials

Mulgrew et al (2007) published a randomized validation study of the diagnosis and management of OSA with a single-channel monitor followed by APAP.⁶ They developed a diagnostic algorithm that had a 94% positive predictive value for moderate-to-severe OSA assessed by PSG. Patients who passed the screening (N=68) were randomized to 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.⁷ Patients (N=76) were included in the study if they had been referred by primary care physicians for evaluation of suspected OSA, were habitual snorers, complained of daytime sleepiness, and had an ESS score of 8 or greater (mean, 13.6). At the end of the 2-week trial, patients were asked to rate the perceived effect of treatment and to indicate whether they had used CPAP for more than 2 hours per night and were willing to continue treatment. Patients without a clear benefit of CPAP received a further evaluation, including clinical assessment and PSG. Compared with PSG, patient responses showed a

sensitivity of 80%, a specificity of 97%, a positive predictive value of 97%, and a negative predictive value of 78%.

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

The racial/ethnic diversity of enrolled patients was not reported in any of the above RCTs. More than 75% of enrolled patients in all 3 trials were men.

Apnea Risk Evaluation System

Nonrandomized Comparative Studies

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

SleepImage System

Randomized Controlled Trials

The SleepImage System is cloud-based software as a medical device that generates AHI from data recorded with a single photoplethysmogram sensor. The SleepImage algorithms calculate heart rate variability, respiration, and oxygen saturation with cardiopulmonary coupling analysis. Hilmisson et al (2020) compared results calculated by the SleepImage System with manually scored PSG in 805 children 5 to 9.9 yrs of age who participated in the Childhood Adenotonsillectomy Trial (CHAT).¹⁰ The CHAT study included 1244 habitually snoring children who were referred for PSG. A total of 805 children had successfully collected data from the sensor, while 439 did not. Of the 805 children with data, 47% were male, 61% were African American, and 29% were White. Concordance between the SleepImage-derived AHI and PSG-derived AHI in the successful recordings is shown in Table 4. Kappa was 0.81, 0.89, and 0.91 for mild, moderate, and severe sleep apnea, respectively. A proposed benefit is that this would be easier for children compared to a test requiring multiple sensors in a sleep laboratory and improve access. Further study in a wider population is needed to evaluate whether this system might be a suitable method for evaluating sleep parameters in the home.

Table 4. Clinical Validity of the SleepImage System

Study	Initial N	Final N	Excluded Samples	Prevalence of Condition	Clinical Validity: Agreement (95% CI)		
					Mild Sleep Apnea AHI > 1.0	Moderate Sleep Apnea AHI > 5.0	High Risk AHI > 10.0
Hilmisson et al (2020) ¹⁰	1244	805	439	64%	0.914 (0.895 to 0.934)	0.967 (0.954 to 0.979)	0.986 (0.978 to 0.994)

AHI: Apnea/Hypopnea Index; CI: confidence interval.

Section Summary: Limited Channel Home Sleep Apnea Testing

The evidence for limited channel home sleep apnea testing (includes type 4 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 PAT, actigraphy, and oxygen saturation).

Summary of Evidence

For individuals who have suspected obstructive sleep apnea (OSA) who receive home sleep apnea testing with at least 3 recording channels, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. The RCTs have reported that home sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone [PAT], actigraphy, and oxygen saturation) is noninferior to testing in the sleep lab for adults with a high pretest probability of OSA and absence of comorbid conditions as determined by clinical evaluation. A positive portable monitoring study with channels that include arterial oxygen saturation, airflow, and respiratory effort has a high positive predictive value for OSA and can be used as the basis for a continuous positive airway pressure (CPAP) trial to determine the efficacy of treatment. A negative portable monitoring study cannot be used to rule out OSA. Patients who have a negative result from portable monitoring or have a positive study but do not respond to CPAP should undergo further evaluation. The evidence is sufficient to determine that the technology results in an 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 PAT, actigraphy, and oxygen saturation, lacks support in the literature. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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 4 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 (PSG), portable sleep monitoring tests, multiple sleep latency tests, and continuous positive airway pressure (CPAP) 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

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Sleep Medicine

In 2017, the American Academy of Sleep Medicine (AASM) published clinical practice guidelines on diagnostic testing for adult OSA.¹¹ AASM provided the following recommendations (Table 5).

Table 5. Recommendations on Diagnostic Testing for Adult OSA

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

In 2021, the AASM published a guidance statement that focuses on indications for follow-up sleep apnea testing with PSG or home sleep apnea tests in patients with OSA.¹² The following clinical guidance statements were provided:

- "Follow-up PSG or HSAT is not recommended for routine reassessment of asymptomatic patients with obstructive sleep apnea on PAP therapy, however, follow-up PSG or HSAT can be used to reassess patients with recurrent or persistent symptoms, despite good PAP [positive airway pressure] adherence.
- Follow-up PSG or HSAT is recommended to assess response to treatment with non-PAP interventions.
- Follow-up PSG or HSAT may be used if clinically significant weight gain or loss has occurred since diagnosis of OSA or initiation of its treatment.
- Follow-up PSG may be used for reassessment of sleep-related hypoxemia and/or sleep-related hypoventilation following initiation of treatment for OSA.
- Follow-up PSG or HSAT may be used in patients being treated for OSA who develop or have a change in cardiovascular disease.
- Follow-up PSG may be used in patients with unexplained PAP device-generated data."

The AASM also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA.¹³ 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).

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.^{14,15} 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%.

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).¹⁶ 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 Heart Association

In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease.¹⁷ The treatment options for OSA and eligibility for their use are described in the statement.

Recommendations for screening for OSA are as follows:

- "We recommend screening for OSA in patients with resistant/poorly controlled hypertension, pulmonary hypertension, and recurrent atrial fibrillation after either cardioversion or ablation."
- "In patients with New York Heart Association class II to IV heart failure and suspicion of sleep-disordered breathing or excessive daytime sleepiness, a formal sleep assessment is reasonable."
- "In patients with tachy-brady syndrome or ventricular tachycardia or survivors of sudden cardiac death in whom sleep apnea is suspected after a comprehensive sleep assessment, evaluation for sleep apnea should be considered."
- "After stroke, clinical equipoise exists with respect to screening and treatment."

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2022) reported on the evidence for screening for OSA in adults and concluded that "the current evidence is insufficient to assess the balance of benefits and harms of screening for obstructive sleep apnea in the general adult population. Evidence on screening tools to accurately detect persons in the general adult population at increased risk of OSA who should receive further testing and treatment is lacking".¹⁸

Medicare National Coverage

In 2001, the Centers for Medicare & Medicaid Services (CMS) published a decision memorandum on CPAP that addressed how to define moderate-to-severe OSA as a guide to a coverage policy for CPAP. This review of the literature suggested there is a risk of hypertension with an Apnea/Hypopnea Index (AHI) greater than 15 events per hour, and thus treatment would be warranted for these patients without any additional signs and symptoms. For patients with an AHI between 5 and 15 events per hour and associated symptoms, CMS concluded that the data from 3 randomized controlled trials demonstrated improved daytime somnolence and functioning in those treated with CPAP.

In March 2009, CMS issued a national coverage decision (CAG-00405N) for the types of sleep testing devices that would be approved for coverage.¹⁹ CMS found that the evidence was sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA:

1. "Type I PSG is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed attended in a sleep lab facility.
2. A Type II or Type III sleep testing device is covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
3. A type IV sleep testing device measuring 3 or more channels, 1 of which is airflow, is covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility.
4. Sleep testing devices measuring 3 or more channels that include actigraphy, oximetry, and PAT, are covered when used to aid the diagnosis of OSA in beneficiaries who have signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility, or attended in a sleep lab facility."

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in April 2023 identified over 100 ongoing studies on the diagnosis of OSA.

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Documentation for Clinical Review

Sleep Studies

Please provide the following documentation:

- Type of sleep study that is being requested
- Reason for requested study
- Completed sleep questionnaires (e.g., Epworth Sleepiness Scale, Berlin Questionnaire, STOP-Bang) if applicable
- Prior Polysomnography or Sleep study reports; if applicable
- Name and type of device used for home sleep study if applicable, including the channels being monitored

Post Service (in addition to the above, please include the following):

- Polysomnography or Home Sleep study reports

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	94660	Continuous positive airway pressure ventilation (CPAP), initiation and management

Type	Code	Description
	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 (e.g., by airflow or peripheral arterial tone), and sleep time
	95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (e.g., 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 (e.g., thoracoabdominal movement)
	95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
	95808	Polysomnography; any age, 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
HCPCS	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

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/03/2009	Policy title change Policy revision with position change Policy combined: <ul style="list-style-type: none"> Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome Obstructive Sleep Apnea Surgeries
06/18/2009	Administrative Review

Effective Date	Action
01/19/2010	Coding Update
10/01/2010	Policy title change from Diagnosis and Treatment Services for Obstructive Sleep Apnea (OSA) and Upper Airway Resistance Syndrome (UARS) Policy revision with position change
01/21/2011	Coding Update
04/12/2011	Coding Update
07/22/2011	Policy revision with position change
08/10/2011	Administrative Update
01/11/2013	Policy criteria clarification and revision
02/22/2013	Coding Update
07/03/2013	Policy criteria clarification and revision
01/30/2015	Policy title change from Obstructive Sleep Apnea - Diagnosis and Management Policy revision with position change effective 3/30/2015
03/30/2015	Policy revision with position change
08/31/2015	Coding update
02/01/2016	Policy revision without position change
03/01/2016	Policy Guideline clarification
02/01/2017	Policy revision without position change
10/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
08/01/2018	Policy revision without position change
02/01/2019	Documentation for Clinical Review clarification
10/01/2019	Policy revision without position change
03/01/2020	Coding update
05/01/2020	Administrative update. Policy statement and guidelines updated.
06/01/2020	Administrative update. Policy statement and guidelines updated.
09/01/2020	Annual review. Policy statement and literature updated.
11/01/2020	Administrative update. Policy statement and guidelines updated.
12/01/2020	Administrative update. Policy statement updated.
01/01/2021	Coding update.
08/01/2021	Annual review. Policy statement, guidelines and literature updated.
09/01/2021	Administrative update.
11/01/2021	Coding update.
03/01/2022	Coding update.
07/01/2022	Coding and Administrative update.
10/01/2022	Annual review. Policy statement, guidelines and literature updated. Policy title changed from Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome to current one. Split Medical Management statements.
05/01/2023	Administrative update.
08/01/2023	Annual review. Policy statement, guidelines and literature updated.
12/01/2023	Administrative update.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent

therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Diagnosis of Obstructive Sleep Apnea Syndrome 2.01.18</p> <p>Policy Statement: Blue Shield of California (BSC) requires an unattended (unsupervised) home sleep apnea test (HSAT) as the initial study for the screening for and diagnosis of <i>moderate to severe</i> obstructive sleep apnea (OSA) in adults unless contraindicated.</p> <p>Prior authorization is not required for HSATs. However, treatment based on HSAT results will not be approved unless the following criteria are met:</p> <ol style="list-style-type: none"> I. Documentation that the device used meets either of the following criteria: <ol style="list-style-type: none"> A. All of the following sensors: <ol style="list-style-type: none"> 1. Nasal pressure 2. Chest and abdominal respiratory inductance plethysmography 3. Oximetry; OR B. Utilization of Peripheral Arterial Tone (PAT) with oximetry and actigraphy II. The individual is at least 18 years old III. There are no contraindications to a home sleep study <p>Note: Although the technologies noted in I.A and B are recommended, the following technologies are acceptable in place of I.A.2. above when nasal pressure and oximetry are also used:</p> <ol style="list-style-type: none"> 1. Single thoracoabdominal RIP belt 2. Single or dual thoracoabdominal polyvinylidene fluoride (PVDF) belts 3. Single or dual thoracoabdominal piezo belts 4. Single or dual pneumatic belts <p>I. Repeat unattended (unsupervised) home sleep apnea test with a minimum of recording channels as described above may be</p>	<p>Diagnosis of Obstructive Sleep Apnea Syndrome 2.01.18</p> <p>Policy Statement: Blue Shield of California (BSC) requires an unattended (unsupervised) home sleep apnea test (HSAT) as the initial study for the screening for and diagnosis of <i>moderate to severe</i> obstructive sleep apnea (OSA) in adults unless contraindicated.</p> <p>Prior authorization is not required for HSATs. However, treatment based on HSAT results will not be approved unless the following criteria are met:</p> <ol style="list-style-type: none"> I. Documentation that the device used meets either of the following criteria: <ol style="list-style-type: none"> A. All of the following sensors: <ol style="list-style-type: none"> 1. Nasal pressure 2. Chest and abdominal respiratory inductance plethysmography 3. Oximetry; OR B. Utilization of Peripheral Arterial Tone (PAT) with oximetry and actigraphy II. The individual is at least 18 years old III. There are no contraindications to a home sleep study <p>Note: Although the technologies noted in I.A and B are recommended, the following technologies are acceptable in place of I.A.2. above when nasal pressure and oximetry are also used:</p> <ol style="list-style-type: none"> 1. Single thoracoabdominal RIP belt 2. Single or dual thoracoabdominal polyvinylidene fluoride (PVDF) belts 3. Single or dual thoracoabdominal piezo belts 4. Single or dual pneumatic belts <p>I. Repeat unattended (unsupervised) home sleep apnea test with a minimum of recording channels as described above may be</p>

POLICY STATEMENT

(No changes)

BEFORE

considered **medically necessary** in adults under **any** of the following circumstances:

- A. To assess efficacy of surgery or oral appliances or devices
- B. To reevaluate the diagnosis of OSA and need for continuous positive airway pressure (CPAP) (e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued)
- C. As a screening tool for individuals who are planning for bariatric surgery and have no evidence of a contraindication to a HSAT

- II. Unattended home sleep studies are considered **investigational** in children (less than 18 years of age).
- III. Repeat unattended HSATs are considered **investigational** when done routinely on sequential nights or within a short time period to make or confirm a diagnosis of OSA or to further evaluate OSA when there are no technical problems that would necessitate a repeat test.

Supervised Polysomnography (PSG) in a Sleep Laboratory

Note: A split-night study, in which moderate-to-severe OSA is documented during the first portion of the study using PSG, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP and should be done when appropriate unless documentation is provided why it cannot or was not done.

- IV. An initial supervised polysomnography (PSG) performed in a [sleep laboratory](#) may be considered **medically necessary** for an individual with a moderate or high pretest probability of OSA in **any** of the following situations:
 - A. A previous home study failed to establish the diagnosis of OSA in an individual with a high pretest probability of OSA
 - B. A previous home study was [technically inadequate](#)
 - C. Failure of resolution of symptoms or recurrence of symptoms during treatment
 - D. When testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious

AFTER

considered **medically necessary** in adults under **any** of the following circumstances:

- A. To assess efficacy of surgery or oral appliances or devices
- B. To reevaluate the diagnosis of OSA and need for continuous positive airway pressure (CPAP) (e.g., if there is a significant change in weight or change in symptoms suggesting that CPAP should be retitrated or possibly discontinued)
- C. As a screening tool for individuals who are planning for bariatric surgery and have no evidence of a contraindication to a HSAT

- II. Unattended home sleep studies are considered **investigational** in children (less than 18 years of age).
- III. Repeat unattended HSATs are considered **investigational** when done routinely on sequential nights or within a short time period to make or confirm a diagnosis of OSA or to further evaluate OSA when there are no technical problems that would necessitate a repeat test.

Supervised Polysomnography (PSG) in a Sleep Laboratory

Note: A split-night study, in which moderate-to-severe OSA is documented during the first portion of the study using PSG, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP and should be done when appropriate unless documentation is provided why it cannot or was not done.

- IV. An initial supervised polysomnography (PSG) performed in a [sleep laboratory](#) may be considered **medically necessary** for an individual with a moderate or high pretest probability of OSA in **any** of the following situations:
 - A. A previous home study failed to establish the diagnosis of OSA in an individual with a high pretest probability of OSA
 - B. A previous home study was [technically inadequate](#)
 - C. Failure of resolution of symptoms or recurrence of symptoms during treatment
 - D. When testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious

POLICY STATEMENT

(No changes)

BEFORE	AFTER
<p>parasomnias, or narcolepsy (see Blue Shield of California Medical Policy: Polysomnography for Non-Respiratory Sleep Disorders)</p> <p>E. Presence of a known comorbidity (a contraindication to HSAT; see Policy Guidelines section) that might alter ventilation or decrease the accuracy of a home sleep apnea test</p> <p>F. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA</p> <p>G. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed</p> <p>H. Pediatric individual (i.e., less than 18 years of age)</p> <p>V. An initial supervised polysomnography (PSG) performed in a sleep laboratory may be considered medically necessary for an individual after OSA has been treated or ruled out by a HSAT, when testing is done to look for other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy (a PSG is often done immediately prior to multiple sleep latency testing even when OSA is not a concern)</p> <p>VI. A repeat, supervised polysomnography (PSG) performed in a sleep laboratory may be considered medically necessary for an individual with a moderate or high pretest probability of OSA in any of the following situations:</p> <p>A. To initiate and titrate CPAP for an adult patient who has clinically significant OSA</p> <p>B. Failure of resolution of symptoms or recurrence of symptoms during treatment</p> <p>C. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA</p> <p>D. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed</p> <p>E. To assess efficacy of adenotonsillectomy for a patient under the age of 18</p> <p>F. To initiate and titrate CPAP for a child with either of the following:</p> <ol style="list-style-type: none"> 1. An AHI or RDI of greater than or equal to 5 events per hour 	<p>parasomnias, or narcolepsy (see Blue Shield of California Medical Policy: Polysomnography for Non-Respiratory Sleep Disorders)</p> <p>E. Presence of a known comorbidity (a contraindication to HSAT; see Policy Guidelines section) that might alter ventilation or decrease the accuracy of a home sleep apnea test</p> <p>F. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA</p> <p>G. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed</p> <p>H. Pediatric individual (i.e., less than 18 years of age)</p> <p>V. An initial supervised polysomnography (PSG) performed in a sleep laboratory may be considered medically necessary for an individual after OSA has been treated or ruled out by a HSAT, when testing is done to look for other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy (a PSG is often done immediately prior to multiple sleep latency testing even when OSA is not a concern)</p> <p>VI. A repeat, supervised polysomnography (PSG) performed in a sleep laboratory may be considered medically necessary for an individual with a moderate or high pretest probability of OSA in any of the following situations:</p> <p>A. To initiate and titrate CPAP for an adult patient who has clinically significant OSA</p> <p>B. Failure of resolution of symptoms or recurrence of symptoms during treatment</p> <p>C. To assess efficacy of surgery or oral appliances/devices if a home sleep study could not confirm or disprove OSA</p> <p>D. To titrate for Adaptive Support Ventilation (ASV) when CPAP or BiPAP have first been tried and failed</p> <p>E. To assess efficacy of adenotonsillectomy for a patient under the age of 18</p> <p>F. To initiate and titrate CPAP for a child with either of the following:</p> <ol style="list-style-type: none"> 1. An AHI or RDI of greater than or equal to 5 events per hour

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>2. An AHI or RDI greater than or equal to 1.5 events per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity</p> <p>VII. Auto-adjusting positive airway pressure (APAP) may be considered medically necessary for the titration of pressure as an alternative to a CPAP titration PSG or CPAP use in adults with clinically significant OSA.</p> <p>VIII. Supervised or unattended home sleep apnea tests that do not meet the above criteria are considered investigational.</p> <p>IX. Multiple sleep latency testing is considered investigational in the diagnosis of OSA.</p>	<p>2. An AHI or RDI greater than or equal to 1.5 events per hour in a patient with excessive daytime sleepiness, behavioral problems, or hyperactivity</p> <p>VII. Auto-adjusting positive airway pressure (APAP) may be considered medically necessary for the titration of pressure as an alternative to a CPAP titration PSG or CPAP use in adults with clinically significant OSA.</p> <p>VIII. Supervised or unattended home sleep apnea tests that do not meet the above criteria are considered investigational.</p> <p>IX. Multiple sleep latency testing is considered investigational in the diagnosis of OSA.</p>