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Diagnosis of Obstructive Sleep Apnea Syndrome

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

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

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Coverage

UNSUPERVISED STUDIES
Initial
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., central sleep apnea, heart failure, chronic pulmonary disease, obesity hypoventilation syndrome, neuromuscular disorders with sleep-related symptoms, injurious or potentially injurious parasomnias, or narcolepsy). The Policy Guidelines section defines high pretest probability.

A single unattended (unsupervised) home sleep apnea test with a minimum of recording channels as described above, **may be considered medically necessary** as a screening tool in

individuals who are scheduled for bariatric surgery and have no evidence of a health condition that might alter ventilation or require alternative treatment (see Policy Guidelines section).

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

Repeat

Repeated 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:

1. To assess efficacy of surgery or oral appliances or devices; OR
2. 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).

SUPERVISED STUDIES

Initial

Supervised polysomnography (PSG) performed in a sleep laboratory **may be considered medically necessary** in individuals with a moderate or high pretest probability of OSA in the following situations:

1. Pediatric individuals (i.e., <18 years of age); OR
2. When individuals do not meet criteria for an unattended home sleep apnea test as described above; OR
3. A previous home study failed to establish the diagnosis of OSA in an individual with a high pretest probability of OSA; OR
4. A previous home study was technically inadequate; OR
5. Failure of resolution of symptoms or recurrence of symptoms during treatment; OR
6. When testing is done to rule out other sleep disorders such as central sleep apnea, injurious or potentially injurious parasomnias, or narcolepsy; OR
7. Presence of a comorbidity that might alter ventilation or decrease the accuracy of a home sleep apnea test, including, but not limited to heart failure, neuromuscular disease, chronic pulmonary disease, or obesity hypoventilation syndrome.

Repeat

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

1. To initiate and titrate CPAP in adults who have:
    - An Apnea/Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of at least 15 events per hour, OR
    - An AHI or RDI of at least 5 events per hour in an individual with 1 or more signs or symptoms associated with OSA (e.g., 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 PSG, followed by CPAP during the second portion of the study, can eliminate the need for a second study to titrate CPAP (see Policy Guidelines section for criteria to perform a split-night study).

2. To initiate and titrate CPAP in children:
   - In pediatric individuals, an AHI or RDI of ≥5; OR
   - An AHI or RDI ≥1.5 in an individual with excessive daytime sleepiness, behavioral problems, or hyperactivity.
3. To assess efficacy of surgery (including adenotonsillectomy) or oral appliances/devices.

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

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

Policy Guidelines

Specialist Training
Polysomnography (PSG) or home sleep apnea testing should be performed in appropriately selected individuals and the test summary results reviewed by a physician 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.

Risk Factors for Obstructive Sleep Apnea
Although not an exclusive list, individuals 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/m^2.

If no bed partner is available to report snoring or observed apneas, other signs and symptoms suggestive of OSA (e.g., age of the individual, 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 individuals 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 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 Respiratory Disturbance Index (RDI) greater than 1.5 events per hour is considered abnormal (an AHI or RDI ≥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 before confirming a diagnosis of narcolepsy with the MSLT.

Split-Night Studies

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

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

Categorization of Polysomnography and Portable Monitoring

Full correspondence does not exist between Current Procedural Terminology (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. Current recommendations are that the portable monitoring device have 4 channels (oxygen saturation, respiratory effort, respiratory airflow, heart rate) and permit review of the raw data. Type 4 monitors with fewer than 3 channels are not recommended due to reduced diagnostic accuracy and higher failure rates. As with attended PSG, it is important that the raw data from home sleep studies be reviewed by a professional trained in sleep medicine to detect artifacts and data loss.

Description

Obstructive Sleep Apnea

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

OSA can also affect the cardiovascular and pulmonary systems. (1) For example, apnea leads to periods of hypoxemia, alveolar hypoventilation, hypercapnia, and acidosis. This, in turn, can cause systemic hypertension, cardiac arrhythmias, pulmonary hypertension, and cor

pulmonale. Systemic hypertension is common in patients with OSA. Severe OSA is also associated with decreased survival, presumably related to severe hypoxemia, hypertension, or an increase in automobile collisions related to daytime sleepiness. It is estimated that about 7% of adults have moderate or severe OSA, 20% have mild OSA, and the referral population of OSA patients represents a small proportion of patients who have clinically significant and treatable disease. (1)

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 1 provides common respiratory events and respiratory event reporting terms and definitions.

Table 1. Definitions of Terms and Scoring Criteria for OSA

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

AHI	The apnea/hypopnea index is the average number of apneas or hypopneas per hour of sleep.
RDI	The respiratory disturbance index is the number of apneas, hypopneas, or respiratory event-related arousals per hour of sleep time. RDI is often used synonymously with the AHI.
REI	The respiratory event index is the number of events per hour of monitoring time. Used as an alternative to AHI or RDI in-home sleep studies when actual sleep time from EEG is not available.
OSA	Obstructive sleep apnea is repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep.
Mild OSA	In adults: AHI or RDI of 5 to <15. In children: AHI ≥1.0 to <5
Moderate OSA	AHI or RDI of 15 to <30; Children: AHI of ≥5 to <10
Severe OSA	Adults: AHI or RDI ≥30; Children: AHI of ≥10
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.
Positive airway pressure	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP.
PAP	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 ≥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.

Regulatory Status

The SleepImage System for diagnosis of OSA is described in Table 2.

Table 2. Other Devices for OSA Diagnosis

Device	Manufacturer	Indications for Use	FDA Marketing Clearance	FDA Product Code	Year
Diagnosis					
SleepImage System	MyCardio	The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality. 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. 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. The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.	K182618	MNR	2019

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

Rationale

Medical policies 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 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.

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 policy.

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 ≥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.

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 policy.

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.

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
Hilmission et al. (2020) (10)	1244	805	439	64%	0.914 (0.895 to 0.934)	0.967 (0.954 to 0.979)	0.986 (0.978 to 0.994)

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

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.

Clinical Input

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/m^2, 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.

Practice Guidelines and Position Statements

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. (11, 12) 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 Academy of Sleep Medicine

In 2017, the American Academy of Sleep Medicine (AASM) published clinical practice guidelines on diagnostic testing for adult OSA. (13) AASM provided the following recommendations (Table 5).

Table 5. Recommendations on Diagnostic Testing for Adult OSA

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

Recommendation Statement	SOR	QOE	Benefits vs 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. (14) 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. (15) 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 Heart Association

In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease. (16) 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."

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). (17) 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…."

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 RCTs 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 2025 identified over 100 ongoing studies on the diagnosis of OSA.

Coding

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

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

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

CPT Codes	94762, 95782, 95783, 95800, 95801, 95805, 95806, 95807, 95808, 95810, 95811
HCPCS Codes	G0398, G0399, G0400

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

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

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

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

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. The following changes were made to Coverage: 1) Modified conditional criteria for unsupervised initial studies; 2) Added “A single unattended (unsupervised) home sleep apnea test with a minimum of recording channels as described above, may be considered medically necessary as a screening tool in individuals who are scheduled for bariatric surgery and have no evidence of a health condition that might alter

	ventilation or require alternative treatment (see Policy Guidelines section).”; 3) Modified conditional criteria for unsupervised repeat studies; 4) Combined adult and pediatric supervised initial studies into one section with modification of conditional criteria; 5) Modified conditional criteria for supervised repeat studies; 6) Combined not medical necessary statements for studies not meeting specified criteria into one single statement; and 7) Removed statement on maintenance of wakefulness testing. Added reference 10; one reference removed.
12/15/2024	Document updated with literature review. Coverage unchanged. References updated; none added or removed.
01/15/2024	Document updated with literature review. The following changes were made to Coverage: 1) Clarified criteria addressing types of monitoring devices for home (unattended/unsupervised) sleep studies; 2) Removed “Limited channel home sleep apnea testing (HST) devices that are unable to calculate apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) (including but not limited to the SleepImage system) are considered experimental, investigational and/or unproven;” 3) Added “ including but not limited to Type IV devices not meeting the above description in all clinical scenarios” to the following statement for Initial and Repeat unattended/unsupervised sleep studies: “Unattended (unsupervised) sleep apnea tests that do not meet criteria are considered not medically necessary; including but not limited to Type IV devices not meeting the above description in all clinical scenarios;” 4) Added the criteria of BMI ≥ 40 to the SUPERVISED STUDIES FOR ADULTS-INITIAL section. Reference number 17 was added, reference 18 was updated, and other references were removed.
02/01/2023	Document updated with literature review. The following changes were made in the Coverage: 1) Coverage and information pertaining to medical management of sleep related breathing disorders moved to medical policy MED204.006; 2) Under Supervised Studies-Repeat “an unsupervised study” replaced with “auto-adjusting positive airway pressure (APAP) treatment”. References 12 and 17 added, others updated. Policy title changed from Diagnosis and Medical Management of Sleep Related Breathing Disorders.
06/01/2022	Document updated with literature review. The following changes were made to Coverage: 1) Removed the following bullet from the SUPERVISED STUDIES FOR ADULTS-INITIAL section: Patients do not meet criteria for an unattended home sleep apnea test as described above; 2) Removed APAP from the following section: Bilevel Positive Airway Pressure or APAP for Obstructive Sleep Apnea (OSA); 3) Replaced NOTE 4 with the following: NOTE 4: Repeat sleep studies (home or attended sleep studies) for a patient with known OSA are not necessary to supply new PAP equipment. The following references were added: 3, 30, and 41.

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

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