

Medical Coverage Policy



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Sleep Testing Services

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[Obstructive Sleep Apnea Treatment Services](#)

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Coverage Policy

Coverage of testing for obstructive sleep apnea and other sleep disorders varies across plans. Please refer to the customer's benefit plan document for coverage details. Even if not addressed in the medical benefit plan, screening for or the evaluation of obstructive sleep apnea or other sleep disorder is considered not medically necessary when obtained as a requirement for employment, insurance or government license purposes in the absence of symptoms suggestive of obstructive sleep apnea or other sleep disorder.

HOME SLEEP APNEA TESTING (HSAT AND IN-FACILITY POLYSOMNOGRAPHY (PSG) ADULT:

A sleep study is considered medically necessary for the diagnosis of suspected obstructive sleep apnea (OSA) in an adult (age 18 or older) when BOTH of the following criteria are met (Refer to the sections below to determine whether in-facility PSG or HSAT is indicated):

- evidence of daytime sleepiness (e.g., excessive sleepiness not explained by other factors, non-refreshing sleep, sleep fragmentation)
- **ANY** of the following additional symptoms or risk factors of OSA:
 - witnessed apneas
 - gasping or choking during sleep
 - habitual snoring
 - increased neck circumference (i.e., > 17 inches in men, > 16 inches in women)
 - obesity (i.e., body mass index $\geq$ 30)

Home Sleep Apnea Test (HSAT):

A HSAT * is considered medically necessary for the diagnosis of OSA in an adult (age 18 or older) when ALL of the following criteria are met:

- study/test equipment meets the minimum definition described in at least one of the following Current Procedural Terminology (CPT) or Health Care Procedure Coding System (HCPCS) codes:
 - 95800: Sleep study, unattended, simultaneous recording: heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone) and sleep time
 - 95801: Sleep study, unattended, simultaneous recording: minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)
 - 95806: Sleep study, unattended, simultaneous recording of heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)
 - 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
- medical necessity criteria for a sleep study for suspected OSA as outlined above have been met
- absence of significant comorbid condition that would be expected to degrade the accuracy of a HSAT, such as any of the following:
 - moderate to severe pulmonary disease, such as chronic obstructive pulmonary disease (COPD), documented on pulmonary function studies (PFTs)
 - moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g., kyphoscoliosis, myasthenia gravis, amyotrophic lateral sclerosis (ALS), post-polio, syndrome, polymyositis, Guillian Barre syndrome)
 - congestive heart failure New York Heart Association (NYHA) Class III or IV (LVEF $\leq$ 45%)
 - obesity hypoventilation syndrome, previously documented (defined as $pCO_2 > 45$ mmHg and $pO_2 < 60$ mmHg on arterial blood gas)
 - pulmonary hypertension
 - chronic opioid medication use
- no sleep disorder other than OSA is suspected (e.g., central sleep apnea, complex; potentially injurious or violent parasomnias, narcolepsy, REM behavior sleep disorder, nocturnal seizures)

***Note: A HSAT is considered to be one study, whether performed during a single night or during two or more consecutive nights. A HSAT protocol that includes a single night recording is adequate for the diagnosis of OSA.**

A follow-up HSAT when the diagnosis of OSA has been established in an adult (age 18 or older) is considered medically necessary when ALL of the following criteria are met:

- testing is to be performed for **ANY** of the following:
 - confirmation of therapeutic benefit following final adjustment of a mandibular repositioning appliance (MRA)
 - assessment of results following surgical treatment for OSA
 - clinical response is insufficient or symptoms return despite a good initial response to oral appliance therapy
 - reassessment of OSA after 10% change in body weight to assess for change in diagnosis or therapy
- no significant oxygen desaturation* during diagnostic sleep study
- absence of comorbid sleep disorder or significant comorbid medical condition, as described above, that would be expected to degrade the accuracy of a HSAT

A Type IV HSAT (HCPCS code G0400) for any indication is considered experimental, investigational or unproven.

A HSAT for any other indication (e.g., to assess the efficacy of PAP therapy) is considered not medically necessary.

In-Facility Polysomnography (PSG)-Full-Night:

Full night in-facility PSG (CPT codes 95808, 95810) is considered medically necessary in an adult (age 18 or older) when BOTH of the following criteria are met:

- medical necessity criteria for a sleep study for suspected OSA as outlined above have been met
- **ANY** of the following:
 - significant comorbid condition that would be expected to degrade the accuracy of a HSAT such as any of the following:
 - o moderate to severe pulmonary disease, such as COPD
 - o moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g., kyphoscoliosis, myasthenia gravis, ALS, post-polio syndrome, polymyositis, Guillian Barre syndrome)
 - o congestive heart failure (moderate to severe) NYHA Class III or IV (LVEF $\leq$ 45%)
 - o obesity hypoventilation syndrome, previously documented (defined as pCO₂ > 45 mmHg and pO₂ < 60 mmHg on arterial blood gas)
 - o pulmonary hypertension
 - o chronic opioid medication use
 - HSAT proved to be technically inadequate or failed to establish the diagnosis of OSA in an individual with high pretest likelihood of OSA performed within the past 90 days
 - individual and caregiver/companion incapable of operating home testing equipment

Full night in-facility PSG (CPT codes 95808, 95810) is considered medically necessary in an adult (age 18 or older) when a sleep disorder other than OSA is suspected (e.g., central sleep apnea, complex; potentially injurious of violent parasomnias, narcolepsy, REM behavior sleep disorder, nocturnal seizures) that is corroborated by the clinical documentation.

Full night in-facility PSG (CPT codes 95808, 95810) or In-Facility PSG-Positive Airway Pressure (PAP) Titration (CPT code 95811) is considered medically necessary prior to a planned multiple sleep latency test (MSLT) in an adult (age 18 or older) with suspected narcolepsy.

In-Facility Polysomnography (PSG) with Initiation of Positive Airway Pressure (PAP) (Split-Night Study):

Split-night in-facility PSG (CPT code 95811), in which the initial diagnostic portion of the PSG is followed by PAP titration, is considered medically necessary in an adult (age 18 or older) when ALL of the following criteria are met:

- medical necessity criteria for a sleep study for suspected OSA as outlined above have been met
- apnea/hypopnea index (AHI), respiratory disturbance index (RDI) or respiratory event index (REI) on HSAT of 15 or higher during initial diagnostic portion of split-night study, or AHI, RDI or REI $\geq$ 5 with symptoms indicative of significant OSA (e.g., repetitive obstructions, significant oxygen desaturation [i.e. oxygen saturation < 80% for >1% of sleep time or < 90% for > 30% of sleep time during a diagnostic facility based PSG or recording time during prior HSAT])
- **ANY** of the following:
 - significant comorbid condition that would be expected to degrade the accuracy of a HSAT such as any of the following
 - o moderate to severe pulmonary disease, such as COPD, documented on PFTs
 - o moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g., kyphoscoliosis, myasthenia gravis, ALS, post-polio syndrome, polymyositis, Guillian Barre syndrome)
 - o congestive heart failure (moderate to severe), NYHA Class III or IV (LVEF $\leq$ 45%)

- o obesity hypoventilation syndrome, previously documented (defined as $pCO_2 > 45$ mmHg and $pO_2 < 60$ mmHg on arterial blood gas)
- o pulmonary hypertension
- o chronic opioid medication use
- HSAT proved to be technically inadequate or failed to establish the diagnosis of OSA in an individual with high pretest likelihood of OSA conducted within the past 90 days
- individual and caregiver/companion incapable of operating home testing equipment

Split-night in-facility PSG (CPT code 95811), in which the initial diagnostic portion of the PSG is followed by PAP titration is considered medically necessary in an adult (age 18 or older) when a sleep disorder other than OSA is suspected (e.g., central sleep apnea, complex; potentially injurious of violent parasomnias, narcolepsy, rapid eye movement (REM) behavior sleep disorder, nocturnal seizures) and is corroborated by the clinical documentation.

In-Facility Polysomnography (PSG)-Positive Airway Pressure (PAP) Titration:

In-facility PSG (CPT code 95811) for PAP titration, following a prior diagnostic study is considered medically necessary in an adult (age 18 or older) when ALL of the following criteria are met:

- AHI or RDI or REI ≥ 15 documented on prior PSG or HSAT, or AHI or RDI or REI ≥ 5 and < 15 , with symptoms of OSA (e.g., excessive daytime sleepiness, impaired cognition, mood disorders or insomnia), or with hypertension, ischemic heart disease or history of stroke
- ANY of the following:
 - a significant comorbid condition that would be expected to degrade the accuracy of a HSAT, such as any of the following
 - o moderate to severe pulmonary disease, such as COPD, as documented on PFTs
 - o moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases (e.g., kyphoscoliosis, myasthenia gravis, ALS, post-polio, polymyositis, Guillian Barre syndrome)
 - o congestive heart failure (moderate to severe), NYHA Class III or IV (LVEF $\leq 45\%$)
 - o obesity hypoventilation syndrome, previously documented (defined as $pCO_2 > 45$ mmHg and $pO_2 < 60$ mmHg on arterial blood gas)
 - o pulmonary hypertension
 - ⊕ individuals with significant oxygen desaturation*

In-facility PSG (CPT code 95811) for PAP titration, following a prior diagnostic study is considered medically necessary in an adult (age 18 or older) when a comorbid sleep disorder (e.g., significant central sleep apnea [i.e., central sleep apneas/hypopneas $> 50\%$ of total apneas/hypopneas, and ≥ 5 central apneas/hypopneas per hour], complex; potentially injurious of violent parasomnias, REM behavior sleep disorder, nocturnal seizures) corroborated by the clinical documentation.

In-facility PSG (CPT code 95811) for re-titration of PAP is considered medically necessary in an adult (age 18 or older) when BOTH of the following criteria are met:

- clinical response to PAP is insufficient or symptoms (e.g., daytime somnolence, snoring) return despite objective compliance** with PAP therapy
- individuals with significant oxygen desaturation* during diagnostic sleep study, or presence of a comorbid sleep disorder or significant comorbid medical condition as described above

* Significant oxygen desaturation:

- O_2 saturation $< 80\%$ for $> 1\%$ of sleep time or $< 90\%$ for $> 30\%$ of sleep time during prior diagnostic facility-based study or recording time during prior HSAT.

**Objective compliance with PAP therapy:

- 70% PAP use for 4 or more hours in a 24 hour period as measured on PAP download data. Insufficient response to therapy: residual AHI of ≥ 5 events per hour, as reported on PAP download data.

Adult in-facility PSG for any other indication is considered not medically necessary.

An abbreviated cardiorespiratory sleep study to acclimate an individual to PAP (e.g., PAP-Nap study, CPT code 95807-52) is considered experimental, investigational or unproven.

IN-FACILITY POLYSOMNOGRAPHY (PSG)-CHILD:

In-Facility PSG:

Pediatric in-facility PSG (CPT codes 95782, 95783, 95808, 95810, 95811) is considered medically necessary for ANY the following indications:

- suspected sleep apnea, including OSA, based on clinical assessment
- following adenotonsillectomy in a child with mild preoperative OSA with residual symptoms of OSA
- following adenotonsillectomy to assess for residual OSA in child with preoperative evidence of moderate to severe OSA, obesity, craniofacial anomalies that obstruct the upper airway, or neurologic disorder (e.g., Down syndrome, Prader-Willi syndrome, myelomeningocele)
- titration of PAP in a child with OSA
- suspected congenital central alveolar hypoventilation syndrome or sleep related hypoventilation due to neuromuscular disorders or chest wall deformities
- primary apnea of infancy
- evidence of a sleep related breathing disorder in infant who has experienced an apparent life threatening event (ALTE)
- child being considered for adenotonsillectomy to treat OSA
- follow-up for child on chronic PAP support, to determine whether pressure requirements have changed due to growth and development; if symptoms recur while on PAP; or if additional or alternate treatment is instituted
- assessment of response to treatment with an oral appliance
- noninvasive positive pressure ventilation (NIPPV) titration in child with other sleep-related breathing disorder (SRBD)
- evaluation of child treated with mechanical ventilation for adjustment of ventilator settings.
- evaluation prior to decannulation in child treated with tracheostomy for SRBD
- clinical suspicion of an accompanying sleep related breathing disorder in a child with chronic asthma, cystic fibrosis, pulmonary hypertension, bronchopulmonary dysplasia, or chest wall abnormality (e.g., kyphoscoliosis)

Pediatric in-facility PSG for any other indication is considered not medically necessary.

HSAT:

A HSAT for the diagnosis of OSA in a child younger than age 18 years is considered experimental, investigational or unproven.

An in-facility PSG or HSAT in an adult or child for any of the following neurological or primary sleep disorders is considered experimental, investigational or unproven (this list may not be all-inclusive):

- chronic lung disease
- circadian rhythm disorders
- depression
- insomnia associated with psychiatric disorders
- restless leg syndrome
- seizures in the absence of symptoms of sleep disorder
- snoring without excessive daytime sleepiness

- transient or chronic insomnia in the absence of symptoms of sleep disorder

OTHER DIAGNOSTIC TESTS:

Maintenance of wakefulness testing (MWT) (CPT code 95805) is considered medically necessary to evaluate response to treatment for obstructive sleep apnea, narcolepsy, or periodic limb movement disorder. The MWT can be performed as a stand-alone test. A preceding PSG (CPT code 95810) or PAP titration (CPT code 95811) is not required and may be performed at the request of the ordering provider.

Multiple sleep latency testing (MSLT) is considered medically necessary for the evaluation of suspected narcolepsy when other sleep disorders have been ruled out by PSG.

MSLT is considered medically necessary for the evaluation of narcolepsy when pharmacotherapy is initiated or continued and a previous MSLT is not available.

MSLT or MWT (CPT code 95805) for the diagnosis of OSA is considered not medically necessary.

The following devices/procedures for the diagnosis of OSA or other sleep disorders in an adult or child are considered experimental, investigational or unproven (this list may not be all-inclusive):

- Actigraphy (CPT code 95803)
- SomnaPatch™
- SleepStrip™

Overview

This Coverage Policy addresses sleep testing services for the diagnosis of sleep disorders.

General Background

Obstructive sleep apnea (OSA) is a treatable form of sleep disordered breathing characterized by repetitive episodes of apnea, hypopnea, or respiratory effort related arousals (RERA) during sleep. Apnea may be obstructive, central, or mixed. With obstructive apnea, airflow is absent or nearly absent, but ventilatory effort persists. With central apnea, both airflow and ventilatory effort are absent, while with mixed apnea, there is an interval with no respiratory effort followed by an interval with obstructed respiratory effort. Hypopnea may be obstructive or central. With obstructive hypopnea, snoring occurs during the event, there is increased inspiratory flattening of the nasal pressure waveform or airflow compared to baseline, or there is associated thoracoabdominal paradox (i.e., asynchronous movement of the thorax and abdomen) during the event that was not present prior to the event. A hypopnea is considered central if none of the criteria for obstructive hypopnea are met during the event. An apneic or hypopneic event by definition lasts at least ten seconds. Most are ten to thirty seconds in duration, and may occasionally persist for one minute or more. RERAs consist of a sequence of breaths that last at least ten seconds, with increasing respiratory effort followed by an arousal from sleep that does not meet the criteria for an apnea or hypopnea.

Sleep is broadly divided into non-rapid eye movement (NREM) sleep, or N sleep, and rapid eye movement (REM) sleep, or R sleep. NREM sleep is further divided into three stages: N1, N2, and N3 sleep. Stage N1 is the typical transition from wakefulness to sleep, and is the lightest stage of sleep. Individuals awakened in this stage usually don't perceive that they were asleep. This stage typically accounts for no more than 10% of total sleep time. The largest percentage of total sleep time, usually 45-55%, is spent in stage N2. Stage N3 is often referred to as deep sleep or slow wave sleep, and usually accounts for 10-20% of total sleep time in young to middle age adults, and decreases with age. This stage tends to occur early in the night, since it represents the homeostatic drive to sleep which is highest after wakefulness. REM sleep, or stage R, is usually the final stage of the sleep cycle in adults. During this stage an EEG will demonstrate a pattern that resembles an active, awake EEG. Rapid eye movements are the defining feature of this stage. REM sleep accounts for 18-23% of sleep time. Respiratory events occur more frequently in stages N1, N2, and R sleep than in stage N3. Events that occur in R

sleep and when the individual is supine are usually longer and associated with more severe oxygen desaturation. REM related muscle atonia may impair upper airway patency, causing increased frequency of obstructive respiratory events.

OSA occurs when the patency of the nasopharyngeal airway becomes insufficient during sleep. Anatomic risk factors include nuchal obesity (cricothyroid neck circumference greater than 17 inches in men or 16 inches in women), deviated septum, nasal polyps, enlarged uvula and soft palate, small chin with deep overbite, enlarged tonsils, and hypertrophy of the lateral pharyngeal musculature. In addition to anatomical predisposition, patients with OSA appear to be unable to maintain oropharyngeal muscle dilator activity during sleep sufficient to prevent airway collapse during the negative pressure of inspiration. Apneas and hypopneas are common during REM sleep, when muscles completely relax. When the pharyngeal muscles relax, the palate may fall backward, and relaxation of the genioglossus muscle at the base of the tongue allows the tongue to fall backward, occluding the airway. The apneic event is terminated by a brief arousal to wakefulness or a lighter stage of sleep, which is accompanied by activation of the upper airway dilator and abductor muscles and restoration of airway patency and other physiologic responses.

Snoring is highly prevalent in adults and children, and it is also the most common symptom of OSA. Snoring that is not accompanied by an AHI ≥ 5 in adults and not associated with reports of excessive daytime sleepiness is referred to as primary snoring. Snoring that is associated with OSA, however, is generally loud and intermittent, and is accompanied by awakening with gasping or choking, sleep fragmentation, restlessness, impaired concentration, and daytime sleepiness. Daytime sleepiness is thought to be related to sleep disruption and may also be related to recurrent hypoxemia. These typical symptoms are not always present or apparent, however. It is not unusual for patients subsequently diagnosed with OSA to initially present with hypertension, arrhythmias, or heart failure. There is mounting evidence that the presence and severity of OSA is associated with increased risk of cardiovascular disease. OSA is thought to play a role in the pathogenesis of systemic hypertension and heart failure and may also be associated with acute coronary syndromes, pulmonary hypertension, arrhythmias, and stroke.

Diagnosis of OSA: Adult

The American Academy of Sleep Medicine (AASM International Classification of Sleep Disorders (ICSD), 3rd edition (2014) includes the following diagnostic criteria for obstructive sleep apnea in adults:

(A and B) or C satisfy the criteria

A. The presence of one or more of the following:

- The patient complains of sleepiness, nonrestorative sleep, fatigue, or insomnia symptoms.
- The patient wakes with breath holding, gasping, or choking.
- The bed partner or other observer reports habitual snoring, breathing interruptions, or both during the patient's sleep.
- The patient has been diagnosed with hypertension, a mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation, or type 2 diabetes mellitus.

B. Polysomnography (PSG) or home sleep apnea test (HSAT) demonstrates:

- Five or more predominantly obstructive respiratory events (obstructive and mixed apneas, hypopneas, or respiratory effort related arousals [RERAs]) per hour of sleep during a PSG or per hour of monitoring (HSAT).

OR

C. PSG or HSAT demonstrates:

- Fifteen or more predominantly obstructive respiratory events (apneas, hypopneas, or RERAs) per hour of sleep during a PSG or per hour of monitoring (HSAT).

The authors noted that HSAT commonly underestimates the number of obstructive respiratory events per hour compared to PSG because actual sleep time, determined primarily by EEG, is often not recorded. The term respiratory event index (REI) may be used to denote event frequency based on monitoring time rather than total

sleep time. Respiratory event related arousals and hypopnea events based on arousals from sleep cannot be scored using HSAT because arousals by EEG criteria cannot be identified.

Respiratory effort related (RERAs) may result in daytime sleepiness, fatigue and inattention despite the absence of apneas or hypopneas. RERAs (> 5 events per hour) associated with daytime sleepiness were previously referred to as upper airway resistance syndrome (UARS) and considered a subtype of OSA. These patients have abnormal sleep and cardiorespiratory changes typical of OSA. According to the ICSD 3rd edition, the term UARS is subsumed under the diagnosis of OSA because the pathophysiology does not significantly differ from that of OSA.

Treatment emergent sleep apnea, also referred to as complex sleep apnea, was not recognized as a sleep related breathing disorder in the AASM ICSD 2nd edition. The ICSD 3rd edition does, however, include treatment-emergent central sleep apnea as a defined type of central sleep apnea, with diagnostic criteria as follows:

Diagnostic Criteria

Criteria A-C must be met

A. Diagnostic PSG shows five or more predominantly obstructive respiratory events (obstructive or mixed apneas, hypopneas or RERAs) per hour of sleep

B. PSG during use of positive airway pressure without a backup rate shows significant resolution of obstructive events and emergence or persistence of central apnea or central hypopnea with all of the following:

- Central apnea-central hypopnea index [CAHI] $\geq$ 5/hour.
- Number of central apneas and central hypopneas is >50% of total number of apneas and hypopneas.

C. The central sleep apnea is not better explained by another CSA disorder (e.g., CSA with Cheyne Stokes breathing or CSA due to a medication or substance

The authors note that a diagnosis of treatment-emergent central sleep apnea does not exclude a diagnosis of OSA. That is, a diagnosis of OSA can be made based on the diagnostic sleep study.

Polysomnography (PSG) and Home Sleep Apnea Test (HSAT)

Polysomnography is the collective process of monitoring and recording physiologic data during sleep. Full-night in-laboratory PSG is considered by most experts as the reference method for evaluating OSA. Based on 1994 American Sleep Disorders Association (now American Academy of Sleep Medicine [AASM]) recommendations, four levels are used to classify the complexity of technology used in the diagnosis of sleep-related breathing disorders. Polysomnography, a Type I study, requires that a technician be present and must include the following recordings at a minimum: electroencephalogram (EEG), electrooculogram (EOG), chin electromyography (EMG), airflow, arterial oxygen saturation, respiratory effort, and electrocardiogram or heart rate. Although not a required component of PSG, anterior tibialis EMG is also useful to assist in detecting movement arousals and may assess periodic limb movements which coexist with sleep-related breathing disorders in many patients.

In a split-night PSG, the initial diagnostic portion of the PSG is followed by positive airway pressure (PAP) titration, based on the apnea-hypopnea index (AHI) during the initial portion of the test. A follow-up PSG may be performed when a diagnosis of OSA is confirmed during a prior full-night PSG, or when confirmed during a split-night study when the PAP titration portion of the study is insufficient.

PSG is not indicated for the diagnosis of chronic lung disease, circadian rhythm disorders, depression, or in cases of typical parasomnias when the diagnosis is clear, for patients with seizures when no symptoms of a sleep disorder are present, or for the diagnosis and treatment of restless leg syndrome. PSG is also not indicated for the routine evaluation of transient insomnia, chronic insomnia, or insomnia associated with psychiatric disorders (Kushida, et al., 2005; Littner, et al., 2002).

As stated above, in 1994 the AASM defined four levels to classify the complexity of technology used in the diagnosis of sleep-related breathing disorders. A Type II study, or comprehensive portable polysomnography, is similar to a Type I study (i.e., PSG), but ECG can be replaced by a heart rate monitor and a technician is not in constant attendance. In a Type III study, referred to as a cardiopulmonary study or modified portable sleep apnea testing, at least four parameters are measured. Minimum requirements include recording of ventilation (at

least two channels of respiratory movement, or respiratory movement and airflow); ECG or heart rate; and oxygen saturation. Personnel are needed for preparation, but the ability to intervene is not required for all studies. A Type IV study, or continuous single or dual bioparameter recording, generally uses oximetry and may employ a second airflow assessment parameter. Type IV devices provide limited information; they do not measure sleep time and cannot distinguish between obstructive and central apneas.

The 1994 classification system was based on the number and type of “leads” used, and was closely aligned with existing Current Procedural Terminology (CPT) codes. Since then, there has been a proliferation of devices that measure various parameters, and many devices do not fall within this classification scheme. In 2011, an AASM task force proposed a more specific and inclusive method of classifying and evaluating sleep testing devices other than PSG. Also in 2011, AASM published Standards for Accreditation of Out of Center Sleep Testing that state that HSAT equipment must meet the minimum definitions described in at least one of the specified sleep testing Current Procedural Terminology (CPT) or Health Care Procedure Coding System (HCPCS) codes currently in use.

Although facility-based PSG is considered by most experts to be the reference method for evaluation of OSA, this does not mean that it is an error-free “gold standard” for the diagnosis of OSA. Such a gold standard would consist of a set of criteria or measurements that distinguish patients with OSA from those without, with small misclassification errors, PSG indices alone, however, are not adequate to classify individuals as those with and without OSA. An AHI suggestive of OSA is not sufficient for the diagnosis of the condition, since the severity of symptoms must be accounted for, and other conditions that affect sleep must be excluded. A gold-standard would also have inherent prognostic ability, since patients with OSA have a different prognosis than those without OSA. AHI is not well correlated with response to CPAP therapy, or compliance with therapy. Thus the increased accuracy of the AHI obtained by facility-based PSG may not be predictive of outcomes (Agency for Healthcare Research and Quality [AHRQ], 2011).

Comparison of portable testing to PSG has been one approach taken to validate portable monitoring. Because there is not a direct correlation of PSG results with clinical symptoms and outcomes, however, determination of an accepted treatment threshold based solely on AHI or any other PSG measurement has not been possible. Lack of such a threshold prevents comparative studies of portable monitor testing to calculate sensitivity, specificity, and likelihood ratios. Simultaneous in-laboratory PSG and portable monitoring recordings may be compared to unattended portable monitoring in the home, but direct comparison of results from PSG and portable monitoring are not closely correlated. This may be due to differences in equipment and testing environments, intra-scorer reliability, and night-to-night variability of AHI.

Because of the limitations of studies directly comparing results of PSG to portable monitoring, comparative effectiveness studies have instead evaluated clinical outcomes of patients managed with portable monitoring at home vs. those managed with PSG. These non-inferiority or equivalency trials compare improvements in quality of life and other outcomes instead of directly comparing sleep test results. Based on the available evidence, diagnosis of OSA based on in-facility PSG does not lead to superior outcomes compared to HSAT in terms of functional improvement, quality of life, blood pressure, and CPAP adherence (Kuna, et al., 2011; Skomro, et al., 2010).

Centers for Medicare and Medicaid (CMS): A National Coverage Determination (NCD) for sleep testing for OSA issued in 2009 concluded that the evidence was sufficient to determine that the results of the sleep tests below can be used to diagnose OSA, that the use of such sleep testing technologies demonstrated improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are reasonable and necessary. The NCD provides the following coverage indications and limitations:

Nationally Covered Indications

- 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.
- Type II or Type III sleep testing devices are covered when used to aid the diagnosis of OSA in beneficiaries who have clinical signs and symptoms indicative of OSA if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility.

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

Nationally Non-Covered Indications

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

SleepStrip™: The SleepStrip (Distar, LLC) is an OSA screening device that incorporates signal detection, acquisition and display in a disposable package. The self-adhesive device is placed on the upper lip at bedtime and adjusted until respiration is detected, as indicated by a flashing light. Two nasal thermistors and one oral thermistor produce flow signals that are processed within the SleepStrip's microprocessor (CPU). The five possible results are as follows: zero (no apneas); one (mild sleep apnea, comparable to sleep lab AHI between 15 and 24); two (moderate sleep apnea, comparable to sleep lab AHI between 25 and 39); three (severe sleep apnea, comparable to sleep lab AHI of greater than 40); and E (error in measurement). The SleepStrip disposable apnea screener received 501(k) FDA-approval on Dec 6, 2000.

Pang et al. (2006) conducted a prospective, nonrandomized cohort study to investigate the role of the SleepStrip in the diagnosis of OSA. Patients with suspected OSA who were scheduled for PSG wore the device at home the night after the PSG. The AHI determined by PSG was compared with the results of the SleepStrip. The sensitivity and specificity of the SleepStrip in diagnosing severe OSA when the AHI was > 40 were 33.3% and 95%, respectively. The sensitivity and specificity of the SleepStrip when the AHI was > 25 were 43.8% and 81.3%, respectively. When the AHI was > 15, the sensitivity and specificity of the test were 54.6% and 70%, respectively. The authors concluded that the SleepStrip has a low correlation with the AHI as measured by PSG, and that further studies are needed before this device can be recommended as a screening tool for the diagnosis of OSA.

SomnaPatch™: The SomnaPatch (Somnarus, Inc.) is a home sleep apnea testing device that consists of a forehead-worn disposable adhesive patch connected to a nosepiece. It uses integrated sensors to measure and record nasal pressure, blood oxygen saturation, heart rate, respiratory effort, sleep duration, and changes in body position. The patch weighs less than one ounce. To date, there are no published trials evaluating the SomnaPatch. This device is currently not FDA-approved (Hayes, 2017; Somnarus, Inc. website).

American Academy of Sleep Medicine (AASM): A task force was commissioned by the Board of the American Academy of Sleep Medicine (AASM) (Collop, et al., 2011) to determine a more specific and inclusive method of classifying and evaluating sleep testing devices other than PSG used as aids in the diagnosis of OSA in the out-of-center setting. The term out-of-center (OOC) sleep testing is used to describe portable monitoring/home sleep apnea testing. The first widely used classification system published by AASM in 1994 placed devices into four categories based on the number and type of "leads" used, and this scheme closely aligned with available Current Procedural Terminology (CPT) codes. Since that time, a plethora of devices have been developed, and many do not fall within this classification scheme. The authors proposed a new classification method that details the types of signals measured. The proposed system categorizes OOC devices based on measurements of Sleep, Cardiovascular, Oximetry, Position, Effort, and Respiratory (SCOPER) parameters. Criteria for evaluating devices was also proposed; in patients with a high pre-test probability of having OSA, the OOC testing device has a positive likelihood ratio of 5 or greater, coinciding with an in-lab PSG-generated AHI of ≥ 5 , and an adequate sensitivity (at least 0.825). Using the above criteria, the authors reviewed peer-reviewed literature on FDA-approved devices that utilize more than one signal. Devices that do not include oximetry were excluded, since oximetry is a mandatory signal for scoring AHI using PSG. The literature was analyzed to answer six questions that address the adequacy of different respiratory and effort sensors and combinations to diagnose OSA. The task force provided the following conclusions in response to the six key questions:

- The literature is inadequate to state with confidence that a thermistor alone without any effort sensor is adequate to diagnose OSA. If a thermal sensing device is used as the only measure of respiration, two effort belts are required as part of the montage, and piezoelectric belts are acceptable in this context.
- Nasal pressure can be an adequate measurement of respiration with no effort measure with the caveat that this may be device specific
- Nasal pressure may be used in combination with either two piezo-electric or respiratory inductance plethysmographic (RIP) belts (but not one piezoelectric belt)
- There is insufficient evidence to state that both nasal pressure and thermistor are required to adequately diagnose OSA.
- Regarding alternative devices to diagnose OSA:
 - The data indicate that peripheral arterial tonometry (PAT) devices are adequate for the proposed use. The device based on cardiac signals shows promise, but more study is required as it has not been tested in the home setting.
 - The device based on end-tidal CO₂ (ETC₂) appears to be adequate for a hospital population.
 - For devices using acoustic signals, the data are insufficient to determine whether the use of acoustic signals with other signals, as a substitute for airflow, is adequate to diagnose OSA.

The taskforce stated that future studies for the evaluation of OOC testing devices would greatly benefit by the use of consistent outcome measures to allow direct comparisons and meta-analyses of studies. Standardized research is needed that report a positive likelihood ratio at the appropriate AHI (i.e., ≥ 5), and scored according to the recommended definitions, while using appropriate research reporting and methodology to minimize bias.

The AASM Clinical Guideline for the Evaluation, Management and Long-Term Care of Obstructive Sleep Apnea in Adults (Epstein, et al., 2009) states that the presence of absence and severity of OSA must be determined before initiating treatment in order to identify those at risk for developing complications of sleep apnea, guide treatment, and provide a baseline to evaluate the effectiveness of subsequent treatment. Diagnostic criteria are based on clinical signs and symptoms established during a comprehensive sleep evaluation, which includes a sleep oriented history and physical examination, and findings established by sleep testing. A comprehensive sleep history should include an evaluation for snoring, witnessed apneas, gasping/choking episodes, excessive sleepiness not explained by other factors, including assessment of sleepiness severity by the Epworth Sleepiness Scale, total sleep amount, nocturia, morning headaches, sleep fragmentation/sleep maintenance, insomnia, and decreased concentration and memory. The guideline also states that particular attention should be paid to the presence of obesity, signs of upper airway narrowing, or the presence of other disorders that can contribute to the development of OSA. Features to be evaluated that may suggest the presence of OSA include increased neck circumference (> 17 in men, and > 16 in women), body mass index (BMI) ≥ 30 , and various physiologic abnormalities that may compromise respiration (e.g., retrognathia, macroglossia, tonsillar hypertrophy, elongated/enlarged uvula).

The 2009 AASM guideline (Epstein et al.) reaffirmed recommendations provided in a 2007 guideline on the use of unattended portable monitoring (Collop et al.). Recommendations are based on a review of the literature and consensus: The guideline states that portable monitoring may be used in the unattended setting as an alternative to PSG for the diagnosis of OSA in patients with a high pretest probability of moderate to severe OSA and no comorbid sleep disorder or major comorbid medical disorders when all the following parameters are met:

- Portable monitoring (PM) for the diagnosis of OSA should be performed only in conjunction with a comprehensive sleep evaluation. Clinical sleep evaluations using PM must be supervised by a practitioner with board certification in sleep medicine or an individual who fulfills the eligibility criteria for the sleep medicine certification examination.
- A PM should, at a minimum, record airflow, respiratory effort, and blood oxygenation.
- The type of biosensors used to monitor these parameters for in-laboratory PSG are recommended for use in portable monitors, and include an oronasal thermal sensor to detect apneas, a nasal pressure transducer to measure hypopneas, oximetry, and ideally, inductance plethysmography for respiratory effort.

- An experienced sleep technician, sleep technologist, or appropriately trained healthcare practitioner must perform the application of PM sensors or directly educate the patient in the correct application of sensors.
- Testing should be performed under the auspices of an AASM accredited comprehensive sleep medicine program with policies and procedures for sensor application, scoring, and interpretation of PM.
- A quality/performance improvement program for PM, including inter-scorer reliability must be in place to assure accuracy and reliability.
- Scoring criteria should be consistent with the current published AASM standards for scoring of apneas and hypopneas.
- Due to the known rate of false negative PM tests, in-laboratory PSG should be performed in cases where PM is technically inadequate or fails to establish the diagnosis of OSA in patients with a high pretest probability.

The AASM commissioned the Adult OSA Quality Measures Workgroup to develop evidence-based quality care measures aimed at optimizing care for adult patients with OSA (Aurora, et al., 2015). The measures are based on the available scientific evidence, focus on public safety, and strive to improve quality of life and cardiovascular outcomes for individual OSA patients. The three outcomes that were selected were as follows: improve disease detection and categorization; improve quality of life; and reduce cardiovascular risk. After selecting these relevant outcomes, a total of ten process measures were chosen that could be applied and assessed for the purpose of accomplishing these outcomes. The supporting evidence for the outcome measure or goal of care aimed at reducing cardiovascular risk in patients with OSA states that reduction in BMI has been clearly shown to reduce OSA severity as well as reduce adverse effects on cardiac performance in obese patients. The supporting evidence and rationale for the process measure of assessment of weight states that “Weight gain has been shown to be related to an increased risk for both developing and worsening OSA and, as a corollary, weight loss has been shown to reduce OSA severity. It is known that obstructive sleep apnea is associated with being overweight. Although not all patients with OSA are overweight, the majority of patients with OSA are overweight. In addition, multiple studies have proven that weight loss can reduce OSA severity. Because of this strong relationship, it is important for healthcare providers managing OSA patients to evaluate the patient’s weight to determine their level of risk”. This process measure and desired outcome is based on moderate evidence and workgroup consensus.

The 2017 AASM Clinical Practice Guideline (Kapur et al.) established clinical practice recommendations for the Diagnosis of Obstructive Sleep Apnea (OSA) in Adults. This guideline is intended for use in conjunction with other AASM guidelines on the evaluation and treatment of sleep-disordered breathing in adults. The diagnosis of OSA was previously addressed in two AASM guidelines, the Practice Parameters for the Indications for Polysomnography and Related Procedures: An Update for 2005 (Kushida et al., 2005) and Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients (Collop, et al., 2007). The 2017 AASM Clinical Guideline addresses optimal circumstances under which attended in-laboratory polysomnography (PSG) or home sleep apnea testing (HSAT) should be performed.

The guideline state a **STRONG** recommendation is one that clinicians should follow under most circumstances. A **WEAK** recommendation reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients. The ultimate judgment regarding propriety of any specific care must be made by the clinician in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.

Good Practice Statements:

- Diagnostic testing for OSA should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up.
- Polysomnography is the standard diagnostic test for the diagnosis of OSA in adult patients in whom there is a concern for OSA based on a comprehensive sleep evaluation.

Recommendations:

- Clinical tools, questionnaires and prediction algorithms not be used to diagnose OSA in adults, in the absence of polysomnography or home sleep apnea testing. (STRONG)
- Polysomnography, or home sleep apnea testing 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)
- If a single home sleep apnea test is negative, inconclusive, or technically inadequate, polysomnography be performed for the diagnosis of OSA. (STRONG)
- Polysomnography, rather than home sleep apnea testing, be used for the diagnosis of OSA in patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia. (STRONG)
- If clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for polysomnography be used for the diagnosis of OSA. (WEAK)
- It is suggested that when the initial polysomnogram is negative and clinical suspicion for OSA remains, a second polysomnogram be considered for the diagnosis of OSA. (WEAK)

Agency for Healthcare Research and Quality (AHRQ): An AHRQ comparative effectiveness review was conducted in 2011 (Balk et al.) to systematically review the evidence on OSA diagnosis and treatment in adults. The key questions focused on OSA screening and diagnosis, treatments, associations between apnea-hypopnea index (AHI) and clinical outcomes, and predictors of treatment compliance. Of the 234 studies that met eligibility criteria, 46 evaluated diagnostic tests. The authors concluded that portable monitors and questionnaires may be effective screening tools, but assessments with clinical outcomes are necessary to prove their value over PSG. This conclusion was based on the following two Key Questions that addressed OSA diagnosis:

Key Question 1

How do different available tests compare in their ability to diagnose sleep apnea in adults with symptoms suggestive of disordered sleep? How do these tests compare in different subgroups of patients, based on race, sex, body mass index, existing non-insulin dependent diabetes mellitus, existing cardiovascular disease, existing hypertension, clinical symptoms, previous stroke, or airway characteristics?

To address this Key Question, three types of comparisons were evaluated: portable monitoring devices (Types II, III, and IV) versus PSG, questionnaires versus PSG or portable monitors, and clinical prediction models versus PSG or portable monitors. Studies included in the 2007 Technology Assessment (discussed below) were not reevaluated. The authors provided the following conclusions:

Portable monitors vs. PSG: The strength of evidence is moderate among 15 quality A, 45 quality B, and 39 quality C studies that Type III and IV monitors may have the ability to accurately predict AHI suggestive of OSA with high positive likelihood ratios and low negative likelihood ratios for various AHI cutoffs in PSG. Type III monitors perform better than Type IV monitors at AHI cutoffs of 5, 10, and 15 events per hour. Analysis of difference vs. average analyses plots suggest that substantial differences in the measured AHI may be encountered between PSG and both Type III and Type IV monitors. Large differences compared to in-laboratory PSG cannot be excluded for all portable monitors. The evidence is insufficient to adequately compare specific monitors to each other.

No recent studies compared Type II monitors with PSG. The prior Technology Assessment concluded that based on three quality B studies, type II monitors used at home may identify AHI suggestive of OSA with high positive likelihood ratios and low negative likelihood ratios, although substantial differences in the AHI may be encountered between type II monitors and facility-based PSG.

Questionnaire vs. PSG

The strength of evidence is low that the Berlin Questionnaire is moderately accurate (sensitivity and specificity generally < 90%) to screen for OSA. The strength of evidence is insufficient to evaluate other questionnaires (TOP, STOP-Bang, ASA Checklist, Epworth Sleepiness Scale, Hawaii Sleep questionnaires).

Clinical Prediction Rules vs. PSG

The strength of evidence is low that some clinical prediction rules may be useful in the prediction of a diagnosis of OSA. Ten different clinical prediction rules have been described (e.g., oropharyngeal morphometric model, pulmonary function data model). While all the models were internally validated, external validation for these predictive rules had not been conducted in the vast majority of the studies.

Key Question 2:

How does phased testing (screening tests or battery followed by full test) compare to full testing alone?

The strength of evidence is insufficient to determine the utility of phased testing, followed by full testing when indicated, to diagnose sleep apnea. Only one study met the inclusion criteria, and this study did not fully analyze the phased testing. The sensitivity and specificity of this phased strategy could not be calculated due to a verification bias; not all participants received PSG testing.

In a discussion of OSA diagnosis, the authors stated that, in theory, OSA is relatively simple to diagnose. PSG, the standard diagnostic test, is inconvenient, resource-intensive, and may not be representative of a typical night's sleep. In addition, there are variations across laboratories in definitions of OSA and in the way results are read and interpreted. AHI, which is used as the single metric to define OSA, can also vary from night to night and does not take into account symptoms, comorbidities, or response to treatment. Numerous portable monitors (evaluated in 99 studies) have been developed for use in non-laboratory settings. These use fewer "channels", or specific physiologic measures than typical 16-channel PSG. Although most of the tested portable monitors fairly accurately predict OSA, it is unclear whether any of these monitors can replace laboratory-based PSG. The evidence suggests that the measured AHI from portable monitors is variable compared with PSG-derived AHI, but the source of this variability is unclear. No studies have evaluated the predictive ability for clinical outcomes or response to treatment by portable monitors.

Future studies of the accuracy or bias of diagnostic tests should focus more on head-to-head comparisons of portable monitors, questionnaires, and predictive rules to determine the optimal tool for use in a primary care setting to maximize initial evaluation of OSA and triage high risk patients for prompt PSG. Direct comparisons among existing alternatives to PSG are more important than the current focus on developing new diagnostic tests.

U.S. Preventive Services Task Force (USPSTF): In a systematic review, for the USPSTF, the AHRQ reviewed the evidence on screening and treating asymptomatic adults or those with unrecognized symptoms for obstructive sleep apnea (OSA) (Jonas, et al., 2017). The Investigators concluded that "There is uncertainty about the clinical utility of all potential screening tools. Although screening with Multivariable Apnea Prediction followed by home portable monitor testing may have promise for distinguishing persons in the general population who are more or less likely to have OSA, current evidence is limited. Multiple treatments for OSA reduce AHI, Epworth Sleepiness Scale, and blood pressure. Although good evidence has established that persons with severe OSA die at twice the rate of controls, trials of CPAP and other treatments have not established whether treatment reduces mortality or improves most other health outcomes, barring evidence of some possible benefit for sleep-related quality of life".

Summary: Facility-Based PSG and Portable Monitoring/Home Sleep Apnea Studies

Although facility-based PSG has been considered the standard method for evaluation of OSA, it cannot be considered the "gold standard", since a true gold standard would include a defined set of criteria or measurements to distinguish patients with OSA from those without OSA. An AHI suggestive of OSA is not sufficient for the diagnosis of the condition, since the severity of symptoms must be accounted for, and other conditions that affect sleep must be excluded. A gold-standard would also have prognostic ability, since patients with OSA have a different prognosis than those without OSA. Although the published evidence comparing PSG with HSAT has demonstrated that PSG more accurately measures AHI, AHI is not well correlated with response to CPAP therapy or compliance with therapy. The increased accuracy of the AHI obtained by facility-based PSG therefore may not be predictive of outcomes. In addition, the precise accuracy of PSG may be impacted by several factors, including inter-reader variability, use of different test instruments, an individual's night to night variability, and ability to sleep in a non-home setting (CMS, 2009).

As diagnostic tests, PSG or home sleep apnea study (HSAT) would not be expected to directly change health outcomes, but would affect outcomes through changes in disease management by actions taken in response to

the test results. The usefulness of a test result is constrained somewhat by the available treatment options. The number of practical treatment options for OSA is limited; most patients are treated with CPAP, and a small number are treated with oral appliances or surgery (CMS, 2009).

There is adequate evidence to demonstrate that portable monitoring/home sleep apnea studies accurately predict AHI suggestive of OSA with high positive likelihood ratios and low negative likelihood ratios in patients with a high pretest probability of OSA. Comparative effectiveness studies that have evaluated clinical outcomes of patients managed with home testing vs. those managed with PSG demonstrated similar outcomes in terms of functional improvement (e.g., sleepiness scores, activity level, vigilance, productivity), and CPAP adherence. Home sleep apnea studies are not indicated, however, for individuals with significant comorbid medical conditions that may degrade the accuracy of portable testing, including moderate to severe pulmonary disease, neuromuscular disease, obesity-hypoventilation syndrome, or heart failure. Home testing has not been evaluated for, and/or does not include the diagnostic data necessary for those suspected of having other sleep disorders.

Most studies of home sleep apnea testing have evaluated Type III devices that measure two respiratory variables (e.g., respiratory movement and airflow), a cardiac variable (e.g., heart rate or an electrocardiogram), and arterial oxyhemoglobin saturation via pulse oximetry. Some devices also include signals that can detect snoring, determine body position, or detect movement. Type IV devices or continuous single or dual bioparameter recording, generally use oximetry and may employ a second airflow assessment parameter. Type IV devices provides limited information; they do not measure sleep time and cannot distinguish between obstructive and central apneas. There is insufficient evidence in the published medical literature to determine the diagnostic accuracy of Type IV studies.

A full night or split night facility-based PSG may be indicated when recent portable monitoring was technically inadequate or failed to establish the diagnosis in an individual with a high pretest probability of OSA; when a sleep disorder other than OSA is suspected, or when a significant comorbid medical condition exists, including moderate to severe pulmonary disease, neuromuscular disease, obesity-hypoventilation syndrome, or heart failure. In-facility PSG may also be indicated for PAP titration; when the PAP titration portion of a prior split-night study was insufficient; or prior to a planned multiple sleep latency test (MSLT) when narcolepsy is suspected.

Subsequent in-facility PSG or HSAT may be indicated when the diagnosis of OSA has been established, in order to assess outcomes following OSA treatment or to evaluate a return of symptoms or inadequate clinical response to treatment.

Multiple Sleep Latency Test (MSLT): The MSLT is used to measure physiological sleep tendency under standardized conditions in the absence of external alerting factors. It is based on the premise that sleep latency reflects the degree of sleepiness. The patient is given four or five opportunities to sleep for up to 20 minutes at two-hour intervals during the day. The mean time to fall asleep is monitored, and it is determined whether the patient has marked sleepiness, usually defined as a mean sleep latency of less than five minutes.

The MSLT is indicated as part of the evaluation of patients with suspected narcolepsy, since the narcoleptic patient, in addition to demonstrating sleepiness, usually experiences two or more episodes of REM sleep during these naps. This is unlikely with other conditions associated with excess sleepiness. The pathophysiology of narcolepsy involves intrusion of aspects of REM sleep (e.g., muscle atonia and dreams) into periods of wakefulness. The test may also be used to evaluate patients with suspected idiopathic hypersomnia to help differentiate between this condition and narcolepsy, and to evaluate response to medications in patients with idiopathic hypersomnia or narcolepsy (Littner, et al., 2005).

The MSLT is not routinely indicated in the initial evaluation and diagnosis of obstructive sleep apnea syndrome, or in assessment of change following treatment with nasal CPAP, nor is it routinely indicated for evaluation of sleepiness in medical and neurological disorders other than narcolepsy, or for insomnia, or circadian rhythm disorders (Littner, et al., 2005).

Maintenance of Wakefulness Test (MWT): The MWT measures the ability to stay awake for a defined period of time in patients with disorders associated with excessive sleepiness.

The MWT may be indicated in the assessment of individuals in whom the inability to remain awake constitutes a safety issue, or in patients with narcolepsy or idiopathic hypersomnia to assess response to treatment (e.g., medications or PAP). Since there is little evidence linking MWT sleep latency results with risk of accidents in real world circumstances, the MWT should be considered an option to be integrated with findings from the clinical history and compliance with treatment (Littner, et al., 2005).

Actigraphy: An actigraph is a small portable device that records movement over an extended period of time and is usually worn on the wrist. Actigraphy measures movement of a limb, and although it may provide an estimate of total sleep time, it does not actually measure sleep or the subjective experience of sleep.

According to updated AASM Practice Parameters for the Use of Actigraphy in the Assessment of Sleep and Sleep Disorders (Morgenthaler, et al., 2007) actigraphy is increasingly used in sleep research and the clinical care of patients with sleep and circadian rhythm abnormalities. The practice parameters state that actigraphy provides an acceptably accurate estimate of sleep patterns in normal, healthy adult populations and in patients suspected of certain sleep disorders. The practice parameters address the use of actigraphy in patients with advanced sleep phase syndrome, delayed sleep phase syndrome, shift work disorder, jet-lag, and non-24 hour sleep/wake syndrome. Regarding OSA, the AASM practice parameters state that, when PSG is not available, actigraphy is indicated as a method to estimate total sleep time in patients with OSA, and that combined with a validated way of monitoring respiratory events, use of actigraphy may improve accuracy in assessing the severity of OSA compared to using time in bed. In recommendations for further research, the practice parameters state that additional research is needed that compares results from different actigraphy devices and the variety of algorithms used to evaluate data in order to further establish standards of actigraphy technology, and that there is a need for additional study addressing the reliability and validity of actigraphy compared to reference standards such as PSG.

There is insufficient evidence in the published medical literature to demonstrate the accuracy of actigraphy in the diagnosis or management of OSA.

Diagnosis of OSA-Child:

The etiology, clinical manifestations and treatment of OSA in the pediatric population differ from those in adults. OSA in children is described in a clinical statement by the American Thoracic Society (ATS) (1996) as a disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnea) that disrupts normal ventilation during sleep and disrupts normal sleep patterns. In children, obstructive apneas of any length are considered abnormal, and children with OSA may demonstrate obstructive hypoventilation or continuous hypopnea associated with hypercapnia, as opposed to discrete obstructive apnea events as seen in adults. During these episodes, increased respiratory effort as evidenced by retractions and/or paradoxical chest movements may be seen. Hypercapnia or oxyhemoglobin desaturation usually accompany these periods of obstructive hypoventilation. The episodes may terminate spontaneously or by arousal from sleep but may last continuously throughout the night.

American Academy of Pediatrics (AAP): An updated AAP Clinical Practice Guideline, Diagnosis and Management of Childhood Obstructive sleep Apnea Syndrome, was published in 2012 (Marcus et al.). The guideline focuses on uncomplicated childhood OSA, i.e., the OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child being treated in the primary care setting. The guideline defines OSA in children, consistent with the ATS definition above) as “a disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnea) that disrupts normal ventilation during sleep and normal sleep patterns”, accompanied by the following symptoms or signs:

- History
 - Frequent snoring (≥3 nights/week)
 - Labored breathing during sleep
 - Gasps/snorting noises/observed episodes of apnea
 - Sleep enuresis (especially secondary enuresis) after at least 6 months of continence
 - Sleeping in a seated position or with the neck hyperextended
 - Cyanosis

- Headaches on awakening
- Daytime sleepiness
- Attention-deficit/hyperactivity disorder
- Learning problems
- Physical examination
 - Underweight or overweight
 - Tonsillar hypertrophy
 - Adenoidal facies
 - Micrognathia/retrognathia
 - High-arched palate
 - Failure to thrive
 - Hypertension

Evidence grading used in the Key Action Statements ranges from A (randomized controlled trials or diagnostic studies on relevant population) to D (expert opinion, case reports, and reasoning from first principles), with an additional category of X (exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm). Recommendations are designated as strong recommendation, recommendation, option, or no recommendation.

The guideline includes the following key action statements regarding testing for OSA:

Polysomnography

If a child or adolescent snores on a regular basis and has any of the [above] complaints or findings, clinicians should either

- obtain a polysomnogram (Evidence Quality A, Key Action strength: Recommendation) OR
- refer the patient to a sleep specialist or otolaryngologist for a more extensive evaluation (Evidence quality D, Key Action strength: Option). (Evidence Quality: Grade A for polysomnography; Grade D for specialist referral, Recommendation Strength: Recommendation.)

Alternative Testing

- If polysomnography is not available, then clinicians may order alternative diagnostic tests, such as nocturnal video recording, nocturnal oximetry, daytime nap polysomnography, or ambulatory polysomnography. (Evidence Quality: Grade C, Recommendation Strength: Option.)

American Academy of Sleep Medicine (AASM): The AASM Position Statement for the use of Home Sleep Apnea Test (HSAT) for Diagnosis of OSA in Children states that use of a home sleep apnea test is not recommended for the diagnosis of obstructive sleep apnea in children. The AASM remarks that for the purposes of this position statement, children are defined as individuals <18 years old. The ultimate judgment regarding propriety of any specific care must be made by the clinician, in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources (Kirk, et al., 2017).

AASM Practice Parameters for the Respiratory Indications for Polysomnography in Children, based on a systematic review of the literature. (Aurora et al., 2011), classifies recommendations as follows:

- Standard: A generally accepted patient-care strategy that reflects a high degree of clinical certainty and generally implies the use of Level 1 evidence or overwhelming Level 2 evidence.
- Guideline: A patient-care strategy that reflects a moderate degree of clinical certainty and implies the use of Level 2 evidence or a consensus of Level 3 evidence
- Option: A patient care strategy that reflects uncertain clinical use and implies inconclusive or conflicting evidence or conflicting expert opinion.

Recommendations for PSG use include the following:

Standard

1. Polysomnography in children should be performed and interpreted in accordance with the recommendations of the AASM Manual for the Scoring of Sleep and Associated Events.
2. Polysomnography is indicated when the clinical assessment suggests the diagnosis of obstructive sleep apnea syndrome (OSAS) in children.
3. Children with mild OSAS preoperatively should have clinical evaluation following adenotonsillectomy to assess for residual symptoms. If there are residual symptoms of OSAS, polysomnography should be performed.
4. Polysomnography is indicated following adenotonsillectomy to assess for residual OSAS in children with preoperative evidence for moderate to severe OSAS, obesity, craniofacial anomalies that obstruct the upper airway, and neurologic disorders (e.g., Down syndrome, Prader-Willi syndrome, and myelomeningocele).
5. Polysomnography is indicated for positive airway pressure (PAP) titration in children with obstructive sleep apnea syndrome.

Guideline

1. Polysomnography is indicated when the clinical assessment suggests the diagnosis of congenital central alveolar hypoventilation syndrome or sleep related hypoventilation due to neuromuscular disorders or chest wall deformities. It is indicated in selected cases of primary sleep apnea of infancy.
2. Polysomnography is indicated when there is clinical evidence of a sleep related breathing disorder in infants who have experienced an apparent life-threatening event (ALTE).
3. Polysomnography is indicated in children being considered for adenotonsillectomy to treat obstructive sleep apnea syndrome.
4. Follow-up PSG in children on chronic PAP support is indicated to determine whether pressure requirements have changed as a result of the child's growth and development, if symptoms recur while on PAP, or if additional or alternate treatment is instituted.

Option

1. Polysomnography is indicated after treatment of children for OSAS with rapid maxillary expansion to assess for the level of residual disease and to determine whether additional treatment is necessary.
2. Children with OSAS treated with an oral appliance should have clinical follow-up and polysomnography to assess response to treatment.
3. Polysomnography is indicated for noninvasive positive pressure ventilation (NIPPV) titration in children with other sleep related breathing disorders.
4. Children treated with mechanical ventilation may benefit from periodic evaluation with polysomnography to adjust ventilator settings.
5. Children treated with tracheostomy for sleep related breathing disorders benefit from polysomnography as part of the evaluation prior to decannulation. These children should be followed clinically after decannulation to assess for recurrence of symptoms of sleep related breathing disorders.
6. Polysomnography is indicated in the following respiratory disorders only if there is a clinical suspicion for an accompanying sleep related breathing disorder: chronic asthma, cystic fibrosis, pulmonary hypertension, bronchopulmonary dysplasia, or chest wall abnormality such as kyphoscoliosis.

Recommendations against PSG Use:

1. Nap (abbreviated) polysomnography is not recommended for the evaluation of obstructive sleep apnea syndrome in children. (Option)
2. Children considered for treatment with supplemental oxygen do not routinely require polysomnography for management of oxygen therapy. (Option)

Regarding HSAT, the guideline states, "Unattended testing outside the sleep laboratory in children has been used predominantly in research settings. There is a paucity of research comparing it to traditional in-laboratory attended sleep studies or other objective clinical outcomes, and there are insufficient data upon which to base reliable clinical recommendations for children at this time."

The authors concluded that current evidence in pediatric sleep medicine indicates that PSG has clinical utility in the diagnosis and management of sleep related breathing disorders, and that accurate diagnosis in the pediatric population is best accomplished by integration of PSG findings with clinical evaluation.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS): A Clinical Practice Guideline: Polysomnography for Sleep-Disordered Breathing Prior to Tonsillectomy in Children (Roland, et al., 2011) provides recommendations for using PSG in assessing children, aged 2 to 18 years, who are candidates for tonsillectomy, with or without adenoidectomy. Recommendations pertaining to indications for PSG include the following:

- Indications for PSG: Before performing tonsillectomy, the clinician should refer children with sleep disordered breathing (SDB) for PSG if they exhibit any of the following: obesity, Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, or mucopolysaccharidoses. This recommendation is based on observational studies with a preponderance of benefit over harm.
- Advocating for PSG: The clinician should advocate for PSG prior to tonsillectomy for SDB in children without any of the comorbidities listed above for whom the need for surgery is uncertain or when there is discordance between tonsillar size on physical examination and the reported severity of SDB. This recommendation is based on observational and case-control studies with a preponderance of benefit over harm.
- Unattended PSG with portable monitoring device: In children for whom PSG is indicated to assess SDB prior to tonsillectomy, clinicians should obtain laboratory-based PSG, when available. This recommendation is based on diagnostic studies with limitations and a preponderance of benefit over harm.

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative: The following recommendations for sleep testing from the American Academy of Sleep Medicine include:

- Avoid polysomnography in chronic insomnia patients unless symptoms suggest a comorbid sleep disorder.
- Don't use polysomnography to diagnose restless legs syndrome, except rarely when the clinical history is ambiguous and documentation of periodic leg movements is necessary.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Home Sleep Apnea Testing

Considered medically necessary when criteria in the applicable policy statements listed above are met in an adult (age 18 or older). Considered Experimental/Investigational/Unproven for the diagnosis of obstructive sleep apnea in a child (less than age 18):

CPT®* Codes	Description
95800	Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis (eg, by airflow or peripheral arterial tone) and sleep time
95801	Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis (eg, by airflow or peripheral arterial tone)
95806 [†]	Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (eg, thoracoabdominal movement)

[†]Note: Considered Experimental/Investigational/Unproven when billed with a Modifier 52 to report SleepStrip™

HCPCS Codes	Description
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

Considered Experimental/Investigational/Unproven:

HCPCS Codes	Description
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels

In-Facility Polysomnography (PSG) Testing

Considered medically necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
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
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 bi-level ventilation, attended by a technologist

Considered Experimental/Investigational/Unproven when used to report an abbreviated cardiorespiratory sleep study to acclimate an individual to PAP (e.g., PAP-Nap study):

CPT® Codes	Description
95807-52	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist (reduced services)

Maintenance of Wakefulness Testing, Multiple Sleep Latency Testing

Considered medically necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness

Actigraphy Testing

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)

SomnaPatch™

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
94799	Unlisted pulmonary service or procedure
99199	Unlisted special service, procedure or report

***Current Procedural Terminology (CPT®) ©2017 American Medical Association: Chicago, IL.**

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