Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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(See policy history boxes for previous effective dates)

Title: Diagnosis of Sleep Disorders

Description/Background

OBSTRUCTIVE SLEEP APNEA

Obstructive sleep apnea (OSA) syndrome is characterized by repetitive episodes of upper airway obstruction due to the collapse of the upper airway during sleep. This causes a drop in blood oxygenation and a 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. OSA is associated with higher mortality because patients with OSA are more likely to have cardiac arrhythmias, coronary artery disease, congestive heart failure, stroke, diabetes, and treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications). 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 individuals 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. During apneic episodes and the brief period of arousal that follows, an individual's snoring abruptly ceases and then resumes when the individual falls

asleep again. 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, or 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 individuals 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, and 20% have at least mild OSA, and individuals referred for evaluation of OSA represent only a small proportion of those 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 individuals. The criterion standard diagnostic test for sleep disorders is a polysomnogram performed in a sleep laboratory.[2] A standard polysomnogram includes EEG, submental electromyogram (EMG) and electrooculogram (to detect rapid eye movement [REM] 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 an 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% decrease in arterial oxygen desaturation (depending on the scoring 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 to <5
Moderate OSA	AHI or RDI of 15 to < 30; Children: AHI of ≥ 5 to <10
Severe OSA	Adults: AHI or RDI ≥30; Children: AHI of ≥10
UARS	Upper airway resistance syndrome is characterized by a partial collapse of the airway and results in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha EEG arousals.
Positive airway pressure	
APAP	Auto-adjusting positive airway pressure may be used either to provide treatment or to determine the most effective pressure for CPAP
PAP	Positive airway pressure (PAP) may be continuous (CPAP) or auto-adjusting (APAP) or bi-level (bi-PAP). CPAP is a more familiar abbreviation 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 individuals 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.

Polysomnography (PSG) or home sleep apnea testing is ordered by a physician or qualified healthcare provider who has evaluated the individual and is managing the medical care of the individual, i.e., either a primary care physician or a specialist. Following the review of the sleep study results, recommendations for the most appropriate medical treatment may be made by the treating physician/QHP, or may be a collaborative effort between the treating physician/QHP and the board-certified sleep medicine physician who interprets the results of the testing.

Facility/Provider Requirements

If an attended sleep study is performed in a non-hospital-based sleep laboratory, the laboratory must be accredited by the American Academy of Sleep Medicine (AASM).

An attended sleep study in a hospital-based sleep testing center must be accredited by AASM or an accreditation organization accepted under the Participating Hospital Agreement.

In order to perform and receive reimbursement for in-center and out-of-center sleep testing, a physician must be board-certified in sleep medicine by the American Board of Medical Specialties or the American Board of Sleep Medicine. Any MD or DO may order a sleep test; however, it must be performed and interpreted by a physician who is board-certified in sleep medicine.

The technician performing the sleep testing must have one of the following certifications:

- American Board of Sleep Medicine, Registered Sleep Technologist, OR

- Board of Registered Polysomnographic Technologists, Registered Polysomnographic Technologist, OR
- National Board for Respiratory Care (any of the following):
  - Certified Pulmonary Function Technologist
  - Registered Pulmonary Function Technologist
  - Certified Respiratory Therapist
  - Registered Respiratory Therapist

Risk Factors for OSA
Although not an exclusive list, individuals with all 4 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 30 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, or unexplained hypertension) may be considered. Objective clinical prediction rules are being developed; however, at present, risk assessment is based primarily on clinical judgment.

The STOP-BANG questionnaire is a method developed for non-sleep specialists to assess the signs and symptoms of OSA (Snore, Tired, Observed apnea, Blood Pressure, BMI, Age, Neck, Gender) and 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] score >30 events per hour). Overnight oximetry has been used by some sleep specialists as a component of the risk assessment but is not adequate for the diagnosis of OSA. Therefore, a follow-up polysomnography (PSG) or home sleep apnea test would still be required to confirm or exclude a diagnosis of OSA.

OSA in Children
The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a body mass index greater than the 90th percentile for the weight/height ratio. Although the definition of severe OSA in children is not well established, an AHI or RDI greater than 1.5 events per hour is considered abnormal (an AHI or RDI of $\geq$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 10% 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 (MWT) is an objective measure of the ability to stay awake under soporific conditions (used to assess occupational safety). The MSLT and MWT are not routinely indicated in the evaluation and diagnosis of OSA or in assessment of change following treatment with continuous positive airway pressure (CPAP). The MSLT may be indicated as part of 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 (characterized by difficult morning awakening, sleep drunkenness and constant somnolence but cataplexy is absent) and narcolepsy. Narcolepsy and OSA can co-occur. Because it is not possible to differentiate the excessive sleepiness caused by OSA and narcolepsy, OSA should be treated before confirming a diagnosis of narcolepsy with the MSLT.

Split-Night Studies
American Academy of Sleep Medicine (AASM) practice parameters indicate 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:

a. An AHI of at least 40 is documented during a minimum of 2 hours of diagnostic PSG. Split-night studies may sometimes be considered at an AHI of 20 to 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.
b. CPAP titration is carried out for more than 3 hours (because respiratory events can worsen as the night progresses).
c. PSG documents that CPAP eliminates or nearly eliminates the respiratory events during rapid eye movement (REM) and non-REM sleep, including REM sleep with the individual in the supine position.
d. A second full night of PSG for CPAP titration is performed if the diagnosis of a sleep-related breathing disorder (SRBD) is confirmed, but criteria b and c are not met.

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.

Surgical management of OSA (i.e., adenotonsillectomy, uvulopalatopharyngoplasty, orthognathic surgery) is discussed in the policy titled “Obstructive Sleep Apnea and Snoring – Surgical Treatment”.

Regulatory Status:

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

Table 2. Novel Devices for OSA Diagnosis

Device	Manufacturer	Description	FDA Marketing Clearance	FDA Product Code	Year
Diagnosis					
SleepImage System	MyCardio	Software as a medical device that provides automated analysis of sleep data from a single photoplethysmogram sensor to aid in the evaluation of sleep disorders.	K163696	MNR	2017

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

Medical Policy Statement

Polysomnography (PSG) is an attended (supervised) sleep study (sleep apnea test) performed in a hospital or freestanding sleep laboratory. The safety and effectiveness of PSG, including a split-night PSG, have been established. It may be considered a useful diagnostic option when indicated.

The safety and effectiveness of an unattended sleep study/sleep apnea test with a minimum of 3 recording channels (using, at a minimum, the following sensors: nasal pressure with chest and abdominal respiratory inductance plethysmography and oximetry; OR using Peripheral Arterial Tone [PAT] with oximetry and actigraphy) in a home setting (home sleep apnea test) have been established. It may be considered a useful diagnostic option when indicated.

The safety and effectiveness of multiple sleep latency testing (MSLT) and maintenance of wakefulness testing (MWT) have been established. It may be a useful tool in diagnosing narcolepsy.

Noninvasive pulse oximetry as a sole test (as an **alternative** to polysomnography or as a cardiorespiratory study for diagnosing sleep related breathing disorders) is considered experimental/investigational. Its effectiveness has not been established.

Inclusionary and Exclusionary Guidelines

INITIAL UNATTENDED (UNSUPERVISED) HOME SLEEP APNEA TEST (HSAT)

This should be performed with a minimum of 3 recording channels (using, at a minimum, the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; OR using Peripheral Arterial Tone [PAT] with oximetry and actigraphy). **Both** of the following criteria need to be met.

1. Individuals 18 years of age or older with high pretest probability for moderate to severe OSA
   a. Observed apneas during sleep; **OR**
   b. A combination of **at least two (2)** of the following:
      - Excessive daytime sleepiness evidenced by an Epworth sleepiness >10, inappropriate daytime napping (e.g., during driving, conversation or eating), or sleepiness that interferes with daily activities and is not explained by other conditions;
      - Habitual snoring or gasping/choking episodes associated with awakenings;
      - Treatment-resistant hypertension (persistent hypertension in an individual taking three or more antihypertensive medications);
      - Obesity, defined as a body mass index (BMI) $\geq$ 30 kg/m^2 or neck circumference defined as >17 inches in men or >16 inches in women
      - Craniofacial or upper airway soft tissue abnormalities
      - Unexplained nocturia not attributable to any other causes or conditions

      OR
   c. History of stroke (more than 30 days previously), transient ischemic attack, coronary artery disease, or sustained supraventricular tachycardic or bradycardic arrhythmias in patients who meet **ONE of 6 criteria listed under "b" above.**
2. No exclusions/contraindications to a home sleep apnea test

Exclusions/Contraindications To HSAT:

- Individuals younger than 18 years of age
- Body mass index (BMI) greater than 33 kg/m^2 and elevated serum bicarbonate level above 28 mmol/L
- Diagnosis suspected or established for **ONE** of the following conditions:
  - Narcolepsy
  - Idiopathic hypersomnia
  - Periodic limb movement disorder (PLMD) when **one** of the following are present: pregnancy, renal failure, iron deficiency anemia, peripheral neuropathy, use of antidepressant or antipsychotic medications, or continued hypersomnia and clinical symptoms of PLMD after sleep disordered breathing is ruled out by home sleep apnea testing
  - Central sleep disorder
  - Parasomnias except bruxism and somniloqui (sleep talking)
  - Nocturnal seizures
- Moderate or severe congestive heart failure – New York Heart Association (NYHA) class III or IV
- Congestive heart failure with a history of ventricular fibrillation or sustained ventricular tachycardia in an individual who does not have an implanted defibrillator
- Moderate or severe chronic pulmonary disease – forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) less than or equal to 0.7 and FEV1 less than 80% of predicted

- Documented neuromuscular disease (e.g., Parkinson's, myotonic dystrophy, ALS) when another individual is not available to assist with application of the home sleep apnea testing equipment
- Chronic opioid use when discontinuation is not an option
- Cognitive or physical impairment that results in inability to apply the home sleep apnea testing equipment when another individual is not available to assist with this task
- Oxygen dependence
- Previous technically suboptimal home sleep apnea test when the reason for the suboptimal study is likely to recur
- Obesity hypoventilation syndrome*

***** Established diagnosis of obesity hypoventilation syndrome defined as a body mass index (BMI) greater than30 kg/m^2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology, or medications. Documentation of hypoventilation requires **ANY** of the following:

- Increase in arterial partial pressure of carbon dioxide [$PaCO_2$] (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes
- Greater than 10 mmHg increase in arterial $PaCO_2$ (or surrogate measure) during sleep (compared to an awake supine value) to a value exceeding 50 mmHg for at least 10 minutes
- Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 consecutive minutes of nocturnal recording time (minimum recording time of 2 hours), recorded while breathing the patient's prescribed fraction of inspired oxygen (FiO_2)

REPEAT UNATTENDED (UNSUPERVISED) FOLLOW-UP HOME SLEEP APNEA TEST FOR INDIVIDUALS WITH ESTABLISHED OSA

This should be performed in individuals with no contraindications to HSAT with a minimum of 3 recording channels using, at a minimum, the following sensors: nasal pressure, chest, and abdominal respiratory inductance plethysmography and oximetry; OR using (Peripheral Arterial Tone [PAT] with oximetry and actigraphy)

Inclusions:

A follow-up home sleep apnea study is considered established for an individual with an established diagnosis of OSA and no contraindication to a home sleep apnea study when **ANY** of the following apply:

- On one occasion following:
  - Upper airway surgery performed to treat OSA and/or improve compliance with PAP therapy
  - Initiation of use of an oral appliance
- To reevaluate the diagnosis of OSA and need for continued CPAP if there is a significant weight loss (defined as 10% of body weight) since the most recent sleep study
- Prior to implantation of a hypoglossal nerve stimulator in a patient who has not had a diagnostic study (home or lab) within the preceding 18 months

INITIAL ATTENDED (SUPERVISED) SLEEP STUDY PERFORMED IN A SLEEP LAB

Individuals with suspected OSA:

Inclusions:

1. Individuals 18 years of age or older with a moderate to high pretest probability for OSA
   a. Observed apneas during sleep; **OR**
   b. A combination of **at least two (2)** of the following:
      - Excessive daytime sleepiness evidenced by an Epworth sleepiness >10, inappropriate daytime napping (e.g., during driving, conversation or eating), or sleepiness that interferes with daily activities and is not explained by other conditions;
      - Habitual snoring or gasping/choking episodes associated with awakenings;
      - Treatment-resistant hypertension (persistent hypertension in an individual taking three or more antihypertensive medications);
      - Obesity, defined as a body mass index (BMI) $\geq$30 kg/m^2 or neck circumference > 17 inches in men or >16 inches in women
      - Craniofacial or upper airway soft tissue abnormalities
      - Unexplained nocturia not attributable to any other causes or conditions

      OR
   c. History of stroke (more than 30 days previously), transient ischemic attack, coronary artery disease, or sustained tachycardic or bradycardic arrhythmias in patients who meet **ONE of 6 criteria listed under "b" above.**

      OR

2. When unattended (unsupervised) home sleep apnea test is contraindicated (see exclusions/contraindications to unattended home sleep apnea test above); **OR**

3. When the initial unattended (unsupervised) study was negative, inadequate (when the reason for the inadequate/suboptimal HSAT is likely to recur on second attempt), equivocal or non-diagnostic and clinical suspicion for OSA remains

<u>Individuals 18 years of age or older with suspected sleep disorders other than OSA:</u>
An in-lab supervised sleep study may be considered when there is suspicion of **ANY** of the following:

- Central sleep apnea
- Narcolepsy
- Nocturnal seizures
- Parasomnia
- Idiopathic hypersomnia
- Periodic limb movement disorder (PLMD)—to support a suspicion of PLMD in this context, **ONE** of the following must be documented: pregnancy, renal failure, iron deficiency anemia, peripheral neuropathy, use of antidepressant or antipsychotic medications, or continued hypersomnia and clinical symptoms of PLMD after sleep disordered breathing is ruled out by home sleep apnea testing
- Nocturnal desaturation (due to severe COPD or certain restrictive thoracic disorders)
- Any of the following conditions (right heart failure, polycythemia, cardiac arrhythmias during sleep, or pulmonary hypertension) when the etiology is unclear

<u>Individuals younger than 18 years of age</u>:

Inclusions:

- Individuals younger than 18 years of age with a moderate to high probability of OSA
  - Habitual snoring in association with **one or more** of criteria below:
    - Restless or disturbed sleep
    - Behavioral disturbance or learning disorders including deterioration in academic performance, attention deficit disorder, hyperactivity

    - Frequent awakenings
    - Enuresis (bedwetting)
    - Growth retardation or failure to thrive; **OR**
  - Excessive daytime somnolence or altered mental status not explained by other conditions; **OR**
  - Polycythemia not explained by other conditions; **OR**
  - Cor pulmonale not explained by other conditions; **OR**
  - Witnessed apnea with duration greater than two (2) respiratory cycles; **OR**
  - Labored breathing during sleep; **OR**
  - Hypertrophy of the tonsils or adenoids in individuals at significant surgical risk such that the exclusion of OSA would allow avoidance of surgery; **OR**
  - Suspected congenital central alveolar hypoventilation syndrome or sleep-related hypoventilation due to neuromuscular disease or chest wall deformities; **OR**
  - Clinical evidence of a sleep-related breathing disorder in infants who have experienced an apparent life-threatening event; **OR**
  - For exclusion of OSA in an individual who has undergone adenotonsillectomy for suspected OSA more than eight (8) weeks previously; **OR**
  - The initial study was inadequate, equivocal or non-diagnostic and the child's parents or caregiver report that the breathing patterns observed at home were different from those during testing.

REPEAT ATTENDED (SUPERVISED) SLEEP STUDY PERFORMED IN A SLEEP LAB:

Individuals 18 years of age or older:

Inclusions:
When OSA has not been established
- Equipment failure or less than six (6) hours of recording.

For an established diagnosis of OSA or other sleep disorders
See "Exclusions/Contraindications to HSAT" above and "Contraindications to the Use of APAP" below.

A follow-up in-lab sleep study is considered established for an individual with a diagnosis of OSA if **ANY** of the following apply:
- On **one** occasion following:
  - Upper airway surgery performed to treat OSA and/or improve compliance with PAP therapy
  - Initiation of use of an oral appliance
- To reevaluate the diagnosis of OSA and need for continued CPAP if there is significant weight loss (defined as 10% of body weight) since the most recent sleep study in an individual with exclusions/contraindications to HSAT
- Prior to implantation of a hypoglossal nerve stimulator in a patient who has not had a diagnostic study (home or lab) within the preceding 18 months
- To optimize device settings on one occasion following insertion of a hypoglossal or phrenic nerve stimulator

A follow-up in-lab sleep study is considered established for an individual with a diagnosis of OSA or other sleep disorder if **ANY** of the following apply:

- To titrate CPAP/BPAP in a patient with a Contraindication to the Use of APAP or for whom an attempt at APAP titration has been unsuccessful
- To titrate CPAP/BPAP in a patient with a Contraindication to the Use of APAP (or has failed APAP re-titration) whose attempted split-night study did not adequately establish appropriate CPAP/BPAP treatment parameters
- To re-titrate CPAP/BPAP in a patient with a Contraindication to the Use of APAP (or has failed APAP re-titration) and has recurrence or worsening of symptoms despite PAP adherence as defined by CMS criteria (use of PAP for at least 4 hours per night on 70% of nights during a consecutive 30-day period.

Contraindications to the Use of Auto-adjusting Positive Airway Pressure (APAP)

- Age 18 years or younger
- Congestive heart failure
- Moderate or severe chronic obstructive pulmonary disease: FEV1/FVC less than or equal to 0.7 and FEV1 less than 80% of predicted
- Chronic opiate use
- Use of supplemental oxygen for 24 hours daily
- Central sleep apnea (defined as having at least 50% central events or more than 5 central events per hour)
- Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis)
- Obesity hypoventilation syndrome defined as a body mass index (BMI) greater than 30 kg/m^2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology, or medications. Documentation of hypoventilation requires **ANY** of the following:
  - Increase in arterial $PaCO_2$ (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes
  - Greater than 10 mmHg increase in arterial $PaCO_2$ (or surrogate measure) during sleep (compared to an awake supine value) to a value exceeding 50 mmHg for at least 10 minutes
  - Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 consecutive minutes of nocturnal recording time (minimum recording time of 2 hours), recorded while breathing the patient's prescribed FiO_2

<u>Individuals younger than 18 years of age:</u>

Inclusions:

- Initial study was inadequate, equivocal or non-diagnostic and the child's parents or caregiver report that the breathing patterns observed at home were different from those during testing.
- A patient with established OSA continues to exhibit persistent snoring or other symptoms of sleep disordered breathing despite PAP adherence as defined by CMS criteria (use of PAP for at least 4 hours per night on 70% of nights during a consecutive 30-dayperiod)
- The patient has undergone adenotonsillectomy more than 8 weeks previously for management of established OSA

- To reevaluate the diagnosis of OSA and need for continued PAP if there is significant weight loss (defined as 10% of body weight) since the most recent sleep study
- To initiate or titrate CPAP or BPAP in a patient whose diagnostic study confirms that the patient is a candidate for positive airway pressure therapy and split-night study has not been performed or was inadequate:
    - In pediatric individuals, an AHI greater than 1.5 is considered abnormal, and an AHI of 10 or more may be considered severe.
- The initial sleep study has led to a diagnosis other than OSA and the repeat study is requested because of a change in clinical status or to assess efficacy after a change in therapy
- Prior to implantation of a hypoglossal nerve stimulator in a patient who has not had a diagnostic study (home or lab) within the preceding 18 months

MUTLIPLE SLEEP LATENCY TESTING (MSLT) AND MAINTENANCE OF WAKEFULNESS TESTING (MWT)

Initial MSLT and/or MWT are considered established for suspected narcolepsy when **BOTH** of the following criteria are met:

- Excessive daytime sleepiness has been present for at least 8 weeks
- The patient has at least **ONE** of the following:
    - Disrupted nocturnal sleep
    - Cataplexy
    - Hallucinations (hypnagogic or hypnopompic)
    - Sleep paralysis
    - The patient has undergone polysomnography (PSG) since the onset of symptoms, and
    - symptoms persist despite adequate treatment of obstructive sleep apnea (if present)

Repeat MSLT and/or MWT are considered established for suspected narcolepsy when **BOTH** of the following criteria are met:

- Previous MSLT/MWT did not provide a diagnosis of narcolepsy
- The patient has continued symptoms suggestive of narcolepsy

Repeat MWT is considered established for occupational safety evaluation when **BOTH** of the following criteria are met:

- The patient has an established diagnosis of a sleep breathing disorder or narcolepsy
- The test is performed while on the current treatment to determine adequacy of therapy

MSLT and/or MWT are considered established for idiopathic hypersomnia when **BOTH** of the following criteria are met:

- Excessive daytime sleepiness has been present for at least 8 weeks
- The patient has at least **ONE** of the following:
    - Difficult morning awakening
    - Prolonged sleep during primary sleep period
    - Sleep drunkenness
    - Frequent non-refreshing daytime naps
    - The patient has undergone PSG or HSAT and symptoms persist despite adequate treatment of obstructive sleep apnea (if present)

NONIVASIVE PULSE OXIMETRY

The effectiveness of noninvasive pulse oximetry as a sole test (as an **alternative** to polysomnography or as a cardiorespiratory study for diagnosing sleep related breathing disorders) is considered **experimental/investigational**. Its effectiveness has not been established.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

95782	95783	95800	95801	95805
95806	95807	95808	95810	95811
G0398	G0399			

Other codes (investigational, not medically necessary, etc.):

94762	E0445	G0400*

*May be covered for Medicare if criteria is met

Note: Code(s) G0398-G0399 may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

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

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

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 diagnosis the condition and to inform a decision on appropriate treatment.

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

Populations

The relevant populations of interest is individuals with suspected OSA.

Interventions

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

Comparators

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

Outcomes

The general outcomes of interest are the number of apneas or hypopneas during sleep, measured by the Apnea/Hypopnea Index (AHI), and subjective symptoms of sleepiness, typically measured with the Epworth Sleepiness Scale (ESS) or the Functional Outcomes of Sleep Questionnaire (FOSQ) (see Table 3).

Table 3. Health Outcome Measures Relevant to OSA

Outcome	Measure	Description	Clinically Meaningful Difference (If Known)
Change in AHI	AHI	Mean change in AHI from baseline to posttreatment	Change from severe-to-moderate or mild OSA
AHI success	Percentage of individuals 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 individuals how likely they are to fall asleep in 8 different situations (e.g., watching TV, sitting quietly in a car, or sitting and talking to someone)	An ESS of ≥10 is considered excessively sleepy
FOSQ	30 questions	Disease-specific quality of life questionnaire that evaluates functional status related to excessive sleepiness	A score of ≥18 is the threshold for normal sleep-related functioning, and a change of ≥2 points is considered a clinically meaningful improvement

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

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

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

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
- Individual/sample clinical characteristics were described
- Individual/sample selection criteria were described.

REVIEW OF EVIDENCE

Systematic Reviews

Balk et al (2011) conducted a comparative effectiveness review for the Agency for Healthcare Research and Quality (AHRQ) on the diagnosis and treatment of OSA in adults. [4] Reviewers found strong evidence that an AHI greater than 30 events per hour is an independent predictor of all-cause mortality, with low or insufficient evidence for an association between AHI and other clinical outcomes. Reviewers found moderate evidence that type 3 and type 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 three recording channels that include respiratory effort, airflow, and oxygen saturation, but not heart rate, are considered by some, including the Centers for Medicare & Medicaid, to be sufficient for home sleep studies. Corral et al (2017) reported a multicenter noninferiority trial of home sleep testing using a 3-channel monitor compared with in-laboratory PSG in 430 patients.[5] Included in the study were patients referred to tertiary hospitals in Spain for suspected OSA, who had snoring or sleep apneas observed by a partner, ESS score of ten or greater, and absence of clinical suspicion of any other sleep pathology. Both groups of patients who were diagnosed with OSA received continuous positive airway pressure (CPAP) titration with a single 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 six-month follow-up. ESS score improved by -4.2 (95% confidence interval [CI], -4.8 to -3.6) in the home sleep testing group and by -4.9 (95% CI, -5.4 to -4.3) in the PSG group. With a noninferiority margin of two points on the ESS, home sleep testing was noninferior to in-laboratory PSG.

Section Summary: Multichannel Home Sleep Apnea Testing

Based on this evidence and society guidelines, portable monitoring with a minimum of four recording channels (including oxygen saturation, respiratory movements, airflow, and electrocardiogram or heart rate), or with a device that measures peripheral arterial tone, actigraphy, and oxygen saturation, for diagnosis of OSA in adults who are at high risk for OSA improves outcomes, when clinical evaluation and follow-up are conducted by a medical professional experienced in the diagnosis and treatment of sleep disorders.

Limited Channel Home Sleep Apnea Testing

Clinical Context and Test Purpose

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

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

Populations

The relevant population of interest is individuals with suspected OSA.

Interventions

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

Comparators

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

Outcomes

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

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

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

Study Selection Criteria

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

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

Review of Evidence

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

Randomized Controlled Trials

Mulgrew et al (2007) published a randomized validation study of the diagnosis and management of OSA with a single-channel monitor followed by auto-adjusting positive airway pressure (APAP).[6] They developed a diagnostic algorithm that had a 94% positive predictive value (PPV) for moderate-to-severe OSA assessed by PSG. Patients who passed the screening (n=68) were randomized to attended in-laboratory PSG with CPAP titration or to 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 empiric approach, using a two-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 two-week trial, patients were asked to rate the perceived effect of treatment and to indicate whether they had used CPAP for more than two hours per night and were willing to continue treatment. Patients without a clear benefit of CPAP received further evaluation, including clinical assessment and PSG. Compared with PSG, patient responses showed a sensitivity of 80%, a specificity of 97%, a positive predictive value of 97%, and a negative predictive value of 78%.

Berry et al (2008) randomized 106 patients referred for a sleep study for suspected OSA at a local Veterans Administration center to portable monitoring followed by APAP or to PSG for diagnosis and treatment.[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 Functional Outcomes of Sleep Questionnaire score, and a machine estimate of residual AHI of 3.5 events per hour in the portable monitoring APAP group and 5.3 in the PSG group.

Apnea Risk Evaluation System

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 (ARES) 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 not included in 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 ages 5 to 9.9 yrs. of age who participated in the Childhood Adenotonsillectomy Trial (CHAT).[10] The CHAT study included 1244 habitually snoring children who were referred for PSG. A total of 805 children had successfully collected data from the sensor. Concordance between the SleepImage-derived AHI and PSG-derived AHI 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 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)

CI: confidence interval

Section Summary: Limited Channel Home Sleep Apnea Testing

The evidence for limited channel home sleep apnea testing (includes type four monitors) in patients who have OSA consists of studies on diagnostic accuracy. A number of questions remain about the ability of these home sleep apnea tests to detect clinically significant OSA without sensors for respiratory effort, airflow, and oxygen saturation (or alternatively, peripheral arterial tone, actigraphy, and oxygen saturation).

SUMMARY OF EVIDENCE

For individuals who have suspected obstructive sleep apnea (OSA) who receive home sleep apnea testing with at least three recording channels, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are test accuracy, symptoms, functional outcomes, and resource utilization. RCTs have reported that home sleep apnea testing (with sensors for respiratory effort, airflow, and oxygen saturation, or alternatively with peripheral arterial tone [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 efficacy of treatment. A negative portable monitoring study cannot be used to rule out OSA. Individuals 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 peripheral arterial tone, actigraphy and oxygen saturation, lacks support in the literature. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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

2014 Input

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

2010 Input

In response to requests, the BCBSA received input from 1 physician specialty society and 6 academic medical centers (8 reviewers) for their 2010 policy update. The input focused on the sensors required for unattended home sleep studies and on diagnosis and treatment of OSA in children. In general, the reviewers supported the requirement that home monitors measure 4 parameters, including respiratory effort, airflow, and oxygen saturation, and that their use be restricted to adults. Some exceptions were noted for specific situations. The update included recommendations from reviewers regarding indications that are specific to pediatric patients.

2009 Input

In response to requests, the BCBSA received input from 5 physician specialty societies (6 reviewers) and 3 academic medical centers while their policy was under review in 2009. Professional society guidelines and position statements were also reviewed. In general, the input supported the use of PSG, portable sleep monitoring tests, multiple sleep latency test,

and CPAP for adults as described in the policy. The update included the reviewer's recommendations for clarifications and modifications to the policy statements.

Practice Guidelines and Position Statements

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

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

Table 5. Recommendations on Diagnostic Testing for Adult OSA

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

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

The AASM considers a technically adequate home sleep apnea test (HSAT) device to incorporate "a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else PAT [peripheral arterial tone] with oximetry and actigraphy." The guidelines refer to the AASM Manual for the Scoring of Sleep and Associated Events for additional information regarding HSAT sensor requirements. 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 individuals with OSA. [12] The following clinical guidance statements were provided:

- "Follow-up PSG or HSAT is not recommended for routine reassessment of asymptomatic individuals with obstructive sleep apnea on PAP therapy, however,

follow-up PSG or HSAT can be used to reassess patients with recurrent or persistent symptoms, despite good PAP [positive airway pressure] adherence.
- Follow-up PSG or HSAT is recommended to assess response to treatment with non-PAP interventions.
- Follow-up PSG or HSAT may be used if clinically significant weight gain or loss has occurred since diagnosis of OSA or initiation of its treatment.
- Follow-up PSG may be used for reassessment of sleep-related hypoxemia and/or sleep-related hypoventilation following initiation of treatment for OSA.
- Follow-up PSG or HSAT may be used in patients being treated for OSA who develop or have a change in cardiovascular disease.
- Follow-up PSG may be used in patients with unexplained PAP device-generated data."

The AASM also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA.[13] The levels of recommendation are “standard” (generally accepted patient-care strategy, with high degree of certainty; level 1 to 2 evidence), “guideline” (moderate degree of clinical certainty; level 2 to 3 evidence), or “option” (uncertain clinical use; insufficient or inconclusive evidence).

American Academy of Pediatrics

The American Academy of Pediatrics (AAP; 2012) published guidelines on the diagnosis and management of uncomplicated childhood OSA associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child treated in the primary care setting, which updated AAP’s 2002 guidelines.[14,15] AAP recommended that all children or adolescents be screened for snoring, and PSG be performed in children or adolescents with snoring and symptoms or signs of OSA as listed in the guideline. If PSG is not available, an alternative diagnostic test or referral to a specialist, may be considered (option). The estimated prevalence rates of OSA in children or adolescents ranged from 1.2% to 5.7%.

American Society of Metabolic and Bariatric Surgery

The American Society of Metabolic and Bariatric Surgery (2012) published guidelines on the perioperative management of OSA (reviewed in October 2015).[16] The guidelines noted that while some reports in the literature have recommended routine screening for OSA prior to bariatric surgery, other reports have suggested clinical screening only does not result in any increase in postoperative pulmonary complications after laparoscopic Roux-en-Y gastric bypass, and that most current surgical practices refer patients with clinical symptoms of OSA for PSG, but do not make this a routine preoperative test prior to bariatric surgery. The society provided, based on the evidence in the literature to date, the following guidelines on OSA in the bariatric surgery patient and its perioperative management:

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

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

Recommendations for screening for OSA are as follows:

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

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (2022) reported on the evidence for screening for OSA in adults and concluded that "the current evidence is insufficient to assess the balance of benefits and harms of screening for obstructive sleep apnea in the general adult population. Evidence on screening tools to accurately detect persons in the general adult population at increased risk of OSA who should receive further testing and treatment is lacking"[18,19]

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov identified over 100 studies on the diagnosis of OSA.

Government Regulations
National:
National Coverage Determination (NCD) for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1)
Effective Date of this Version 3/3/2009
Implementation Date 8/10/2009

Indications and Limitations of Coverage

B. Nationally Covered Indications
Effective for claims with dates of service on and after March 3, 2009, the Centers for Medicare & Medicaid Services finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA, that the use of such sleep testing technologies demonstrates improved health outcomes in Medicare beneficiaries who have OSA and receive the appropriate treatment, and that these tests are thus reasonable and necessary under section 1862(a) (1) (A) of the Social Security Act.

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. 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.
3. 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.
4. 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.

C. 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.

Revision History
07/2009 - Previously, although CPAP was nationally covered for beneficiaries with OSA if diagnosed with specific tests, coverage of the tests themselves was left to local contractor discretion. As a result of this recent NCD, effective for claims with dates of service on and after March 3, 2009, Medicare will allow for coverage of the sleep testing devices, specifically: Type 1 PSG when the test is attended in a sleep lab facility, Type II or Type III if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility, or Type IV measuring 3 or more channels, one of which is airflow, if performed unattended in or out of a sleep lab facility or attended in a sleep lab facility. Effective Date: 03/03/2009 Implementation Date: 08/10/2009 (TN 103) (CR6534)

Local:

Wisconsin Physicians Service Insurance Corporation (WPS)
Local Coverage Determination (LCD): Polysomnography and Other Sleep Studies (L36839)
Original Effective Date: For services performed on or after 02/16/2017
Revision Effective Date: For services performed on or after 07/27/2023

Coverage Indications, Limitations, and/or Medical Necessity
Sleep Studies and Polysomnography (PSG) refers to the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep furnished in a sleep laboratory facility that includes physician review, interpretation and report. A technologist is physically present to supervise the recording during sleep time and has the ability to intervene, if needed. The studies are performed to diagnose a variety of sleep disorders and to evaluate a patient's response to therapies such as continuous positive airway pressure (CPAP). PSG is distinguished from sleep studies by the inclusion of sleep staging.

Please refer to CMS publication 100-02 *Medicare Benefit Policy Manual*, Chapter 15 Covered Medical and Other Health Services, Section 70 Sleep Disorder Clinics for guidance: sleep disorder clinics may be hospital-affiliated or freestanding clinics, for conditions diagnosed through the study of sleep, therapy and research which are covered under Medicare.

Polysomnography Testing
Polysomnography (PSG) includes sleep staging, which requires items 1 through 3 below. Polysomnography is defined to minimally include, but is not limited to, the following:

1. A 1-4 lead electroencephalogram (EEG) to measure global neural encephalographic activity using electrodes placed on the scalp.
2. Electrooculogram (EOG) to measure eye movements using electrodes placed near the outer canthus of each eye.
3. A submental electromyogram (EMG) to measure submental electromyographic activity using electrodes placed over the mentalis, submentalis muscle, and/or masseter regions.
4. Rhythm electrocardiogram (ECG).
5. Nasal and/or oral airflow via both thermistor and nasal pressure sensor.
6. Respiratory effort by chest-wall and abdominal movement measured using respiratory inductive plethysmography, endoesophageal pressure or intercostal EMG.
7. Gas exchange (oxygen saturation [SpO2]) by oximetry or transcutaneous monitoring.
8. Bilateral anterior tibialis muscle activity, motor activity-movement using EMG.
9. Body positions by directly applied sensors or by direct observation.

PSG and other sleep test monitoring devices are generally classified based on the number of biologic sensors applied and physiologic parameters recorded.

A. **Criteria for Coverage of Diagnostic Tests**
Please refer to CMS publication 100-02 *Medicare Benefit Policy Manual*, Chapter 15 Covered Medical and Other Health Services, Section 70 Sleep Disorder Clinics, Subsection A. Criteria for Coverage of Diagnostic Tests and Subsection B. Medical Conditions for Which Testing is Covered.

In order to bill claims for diagnostic tests the reasonable and necessary medical conditions will be covered when listed criteria is met:
• Sleep disorder clinics may be hospital-affiliated or freestanding clinics with physician direction and control. Routine diagnostic sleep testing may be performed in the absence of physician direct supervision.
• Sleep disorder clinics will maintain the attending physician’s orders/referrals.
• Documentation will support the medical evidence for the need of diagnostic testing, e.g., the signs, symptoms, concerns, or complaints in order for diagnostic testing to be covered, e.g., physician examinations and laboratory tests.

The Social Security Act 1862(a)(1)(A) does not support duplicative diagnostic testing by the attending physician to the extent the results remain pertinent, as not reasonable and necessary.

B. **Medical Conditions for Which Testing is Covered**

- **Sleep Apnea** - Apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation. This is a potentially lethal condition where the patient stops breathing during sleep. Three types of sleep apnea have been described (central, obstructive, and mixed). The nature of the apnea episodes can be documented by appropriate diagnostic testing.

Diagnostic testing is covered only if the patient has the symptoms or complaints of one of the conditions listed below.

1. Obstructive Sleep Apnea (OSA) is the collapse of the oropharyngeal walls and the obstruction of airflow occurring during sleep. CMS PUB *100-03 NCD* Chapter 1, Section 240.4.1 – Sleep Testing for Obstructive Sleep Apnea (OSA) finds that the evidence is sufficient to determine that the results of the sleep tests identified below can be used by a beneficiary's treating physician to diagnose OSA.

a. **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.
   - The most comprehensive is designated Type I attended facility based polysomnography (PSG), which is considered the reference standard for diagnosing OSA. Attended facility based polysomnogram is a comprehensive diagnostic sleep test including at least electroencephalography (EEG), electro-oculography (EOG), electromyography (EMG), heart rate or electrocardiography (ECG), airflow, breathing/respiratory effort, and arterial oxygen saturation (SaO2) furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed.
   - Overnight PSG is the conventional diagnostic test for OSA. The American Thoracic Society and the American Academy of Sleep Medicine have recommended supervised PSG in the sleep laboratory over 2 nights for the diagnosis of OSA and the initiation of continuous positive airway pressure (CPAP).

b. **Type II 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 II monitors have a minimum of 7 channels (e.g., EEG, EOG, EMG, ECG-heart rate, airflow, breathing/respiratory effort, SaO2)-this type of device monitors sleep staging, so AHI can be calculated).

c. **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 III monitors have a minimum of 4 monitored channels including ventilation or airflow (at least two channels of respiratory movement or respiratory movement and airflow), heart rate or ECG, and oxygen saturation.

d. **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.
   - Type IV devices may measure one, two, three or more parameters but do not meet all the criteria of a higher category device.
   - 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.

2. Narcolepsy - *This term refers to a syndrome that is characterized by abnormal sleep tendencies, e.g., excessive daytime sleepiness or disturbed nocturnal sleep. Related*

diagnostic testing is covered if the patient has inappropriate sleep episodes or attacks (e.g., while driving, in the middle of a meal, in the middle of a conversation), amnesiac episodes, or continuous disabling drowsiness. CMS Publication *100-02, Medicare Benefit Policy Manual*, Chapter 15, Section 70.

e. The diagnosis of narcolepsy is usually confirmed by an overnight sleep study (polysomnography) followed by a multiple sleep latency test (MSLT). MSLT involves several 20-minute nap opportunities offered at 2-hour intervals. MSLT objectively assesses sleep tendency by measuring the number of minutes it takes the patient to fall asleep. Conversely, the maintenance of wakefulness test (MWT) requires the patient to try to stay awake.
f. MSLT is the better test for demonstration of sleep-onset REM periods, a determination that is important in establishing the diagnosis of narcolepsy. To insure validity, proper interpretation of the MSLT can only be made following a polysomnography performed on the preceding night.
g. The following measurements are normally required to diagnose narcolepsy:
    - Polysomnographic assessment of the quality and quantity of nighttime sleep;
    - Determination of the latency of the first REM episode
    - MSLT; and
    - The presence of REM-sleep episodes.
h. Initial polysomnography and MSLT occasionally fail to identify narcolepsy. Repeat polysomnography may be indicated:
    - if the first study is technically inadequate due to equipment failure;
    - if the subject could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;
    - if initiation of therapy or confirmation of the efficacy of prescribed therapy is needed; **or**
    - if the results were inconclusive or ambiguous.

3. Impotence – will not be addressed in this LCD. See CMS Publication *100-02, Medicare Benefit Policy Manual*, Chapter 15, Section 70 for coverage of impotence.

4. Parasomnia - Parasomnias are a group of conditions that represent undesirable or unpleasant occurrences during sleep. Behavior during these times can often lead to damage to the surroundings and injury to the patient or to others. Parasomnia may include conditions such as sleepwalking, sleep terrors, and rapid eye movement (REM) sleep behavior disorders. In many of these cases, the nature of these conditions may be established by careful clinical evaluation. Suspected seizure disorders as possible cause of the parasomnia are appropriately evaluated by standard or prolonged sleep EEG studies. In cases where seizure disorders have been ruled out and in cases that present a history of repeated violent or injurious episodes during sleep, polysomnography may be useful in providing a diagnostic classification or prognosis.

C. Split-Night Studies

1. For Continuous Positive Airway Pressure (CPAP) titration, a split-night study (initial diagnostic polysomnogram followed by CPAP titration during polysomnography on the same night) is an alternative to one full night of diagnostic polysomnography, followed by a second night of titration for the treatment of obstructive sleep apnea (OSA) if the following criteria are met.

Continuous Positive Airway Pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

2. A positive test for OSA is established if either of the following criteria using the Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) are met:
   - AHI or RDI greater than or equal to 15 events per hour with a minimum of 30 events; **or**
   - AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.
     The AHI is equal to the average number of episodes of apnea and hypopnea per hour. The RDI is equal to the average number of respiratory disturbances per hour.

     If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing is at least the number of events that would have been required in a 2-hour period.

   - CPAP titration is carried out for more than three hours; **and**
   - Polysomnography documents that CPAP eliminates, or nearly eliminates, the respiratory events during REM and NREM sleep.

D. Follow-up polysomnography or a cardio-respiratory sleep study is indicated for the following conditions:
- To evaluate the response to treatment (CPAP, oral appliances or surgical intervention);
- After substantial weight loss has occurred in patients on CPAP for treatment of sleep-related breathing disorders to ascertain whether CPAP is still needed at the previously titrated pressure;
- After substantial weight gain has occurred in patients previously treated with CPAP successfully, who are symptomatic again despite continued use of CPAP, to ascertain whether pressure adjustments are needed; or
- When clinical response is insufficient or when symptoms return despite a good initial response to treatment with CPAP.

E. Home Sleep Testing
- The physician services related to home sleep testing (G0398, G0399 and G0400) are covered for the purpose of testing a patient for the diagnosis of obstructive sleep apnea if the home sleep testing is reasonable and necessary for the diagnosis of the patient's condition, meets all other Medicare requirements, and the physician who performs the service has sufficient training and experience to reliably perform the service.
  (See Physician requirements below) (See Billing and Coding: **POLYSOMNOGRAPHY** and Other Sleep Studies)
- A home sleep test is covered only when it is performed in conjunction with a comprehensive sleep evaluation and in patients with a high pretest probability of moderate to severe obstructive sleep apnea.

- Home sleep testing is not covered for persons with comorbidities (moderate to severe pulmonary disease, neuromuscular disease or congestive heart failure).
- Home Sleep studies are only covered for the diagnosis of Obstructive Sleep Apnea. They are not covered for any other sleep disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders or narcolepsy) or for screening asymptomatic persons.

F. Physician and Technician Requirements for Sleep Studies and Polysomnography Testing:

1. **The physician performing the service must meet one of the following:**
   a. be a diplomate of the American Board of Sleep Medicine (ABSM);
      OR
   b. has a Sleep Certification issued by **ONE** of the following Boards:
      American Board of Internal Medicine (ABIM),
      American Board of Family Medicine (ABFM),
      American Board of Pediatrics (ABP),
      American Board of Psychiatry and Neurology (ABPN),
      American Board of Otolaryngology (ABOto),
      American Osteopathic Board of Neurology and Psychiatry (AOBNP),
      American Osteopathic Board of Family Medicine, (AOBFP)
      American Osteopathic Board of Internal Medicine, (AOBIM)
      American Osteopathic Board of Ophthalmology and Otorhinolaryngology (AOBOO);
      OR
   c. be an active physician staff member of a credentialed sleep center or laboratory that have active physician staff members meeting the criteria above in **a** or **b**.

2. **Technician Credentials**
   The technician performing the service must meet one of the following:
   a. American Board of Sleep Medicine (ABSM),
      Registered Sleep Technologist (RST);
   b. Board of Registered Polysomnographic Technologists (BRPT),
      Registered Polysomnographic Technologist (RPSGT);
   c. National Board for Respiratory Care (NBRC)
      Certified Pulmonary Function Technologist (CPFT)
      Registered Pulmonary Function Technologist (RPFT)
      Certified Respiratory Therapist (CRT)
      Registered Respiratory Therapist (RRT)

G. Sleep Center or Laboratory Credentials (this is any site or place of service other than patient's home where sleep studies or recordings are performed)

- The sleep facility credentials must be from the American Academy of Sleep Medicine (AASM), inpatient or outpatient; **OR**
- The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sleep specific credentials for Ambulatory care sleep centers; **OR**
- Accreditation Commission for Health Care (ACHC)
- All centers billing sleep studies must maintain proper certification documentation as defined above.

- The sleep clinic must be affiliated with a hospital or be under the direction and control of a physician (MD/DO), even though the diagnostic test may be performed in the absence of direct physician supervision. This information must be documented and available upon request.
- Sleep disorder clinics may at times render therapeutic as well as diagnostic services. CMS Publication *100-02, Medicare Benefit Policy Manual*, Chapter 15, Section 70, D. Coverage of Therapeutic Services

Non-covered Services

A. **Polysomnography for Chronic Insomnia Is Not Covered.**
The use of polysomnography for diagnosis of patients with chronic insomnia is not covered under Medicare because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

B. **Actigraphy Testing:**
Actigraphy measures movement of a limb.
It can be measured as part of a sleep test but will not be paid for separately.

C. **Polysomnography or a MSLT is not covered in the following situations:**
1. for the diagnosis of patients with chronic insomnia;
2. to preoperatively evaluate a patient undergoing a laser assisted uvulopalatopharyngoplasty without clinical evidence that obstructive sleep apnea is suspected;
3. to diagnose chronic lung disease (Nocturnal hypoxemia in patients with chronic, obstructive, restrictive, or reactive lung disease is usually adequately evaluated by oximetry. However, if the patient's symptoms suggest a diagnosis of obstructive sleep apnea, polysomnography is considered medically necessary);
4. in cases where seizure disorders have not been ruled out;
5. in cases of typical, uncomplicated, and non-injurious parasomnias when the diagnosis is clearly delineated;
6. for patients with epilepsy who have no specific complaints consistent with a sleep disorder;
7. for patients with symptoms suggestive of the periodic limb movement disorder or restless leg syndrome unless symptoms are suspected to be related to a covered indication;
8. for the diagnosis of insomnia related to depression;
9. for the diagnosis of circadian rhythm sleep disorders (i.e., rapid time-zone change [jet lag], shift-work sleep disorder, delayed sleep phase syndrome, advanced sleep phase syndrome, and non-24-hour sleep wake disorder).

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Actigraphy
- Home Cardiorespiratory Monitoring For Pediatrics
- Obstructive Sleep Apnea and Snoring - Surgical Treatment

- Obstructive Sleep Apnea – Non-surgical Treatment

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through August 29, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/10/02	7/10/02	7/10/02	Joint policy established
2/27/03	2/27/03	3/4/03	Criteria updated
4/11/05	4/11/05	4/11/05	Routine review
11/15/05	11/15/05	11/15/05	Code update
7/1/07	6/24/07	6/24/07	Updated policy
1/1/09	10/13/08	10/13/08	Routine maintenance, added home sleep test codes, title change
9/1/09	6/16/09	6/16/09	Code Updates
5/1/10	2/16/10	2/16/10	Code update – 0203T and 0204T added to policy.

			Updated description, rationale, criteria and references. Policy title changed to “Sleep Disorders, Diagnosis and Medical Management”. Previous title, “Obstructive Sleep Apnea (OSA) Diagnosis and Management”.
5/1/11	2/15/11	3/3/11	Routine maintenance; code update – deleted CPT codes 0203T and 0204T; added CPT codes 95800 and 95801
7/1/13	4/16/13	4/22/13	Routine maintenance, Code updates

8/1/16	4/19/16	5/23/16	• Routine maintenance
			• Updated all policy sections
			• Added negative oral pressure therapy – replacing JUMP policy “Negative Oral Pressure Therapy for the Treatment of OSA”
			• Moved codes 95801, E0485 & G0400 from established to investigational
			  ○ HST with type IV portable monitor with 3 channels not covered
			  ○ Prefabricated intraoral appliances not covered
			• Removed divergence from BCBSA – now aligned

7/1/17	4/18/17	4/18/17	• Routine maintenance • Description, rationale, Medicare information and references updated
7/1/18	4/17/18	4/17/18	• Routine maintenance • Description/rationale added for nasal EPAP and oral pressure therapy. E/I indications added.
1/1/19	10/16/18	10/16/18	• Routine maintenance • Accreditation language added; responses to AASM input added.
1/1/20	10/15/19		• Routine maintenance • Minimum of 3 channels for testing; updated MPS, inclusions and exclusions

			• Non-invasive ear and pulse oximeter added to policy (E/I for diagnosis) • Lunoa SPT system (E/I for treatment) • Addition of unexplained nocturia as symptoms • Medicare section updated
1/1/21	10/20/20		Routine maintenance Added Ref 3,10,33
3/1/21	1/5/21		Incorporated IMP “Management of Obstructive Sleep Apnea Syndrome with Oral Appliances”
7/1/21	4/20/21		Exclusions to home sleep studies were updated based upon request from BCN team. They are requesting our policy be more aligned with AIM criteria. Under exclusions for home sleep testing added the below: Added parameters for CHF and COPD Added criterion of inability of individual to apply the home sleep testing equipment Requesting additional exclusions: oxygen dependence Requesting additional exclusions: nocturnal seizures Requesting additional exclusions: Congestive heart failure with a history of ventricular fibrillation or sustained ventricular tachycardia in an individual who does not have an implanted defibrillator
7/1/22	4/19/22		• Revised the definition of hypopnea to “at least 3% or 4% arterial oxygen saturation” in Table 1 in order to reflect both AASM and Medicare requirements. • 3/3/22 Request from BCN team to add additional criteria exclusion under home sleep study as these are contraindicated for a Home Sleep Test. • History of seizures with use of anticonvulsants • Cardiac conditions • Restless leg syndrome

7/1/23	4/26/23		• 4/18/23 Followed BCBSA – Sleep Disorders – Diagnosis and Medical Management was split. This JUMP policy is now called Diagnosis of Obstructive Sleep Apnea Syndrome. Information regarding treatment of OSA was moved to the new Medical Management of Obstructive Sleep Apnea Syndrome policy **now** called Medical Management of Obstructive Sleep Apnea Syndrome (Oral Appliances and Novel Therapies). • Moved codes E0486, E1399, A7047, E0485, K1028, and K1029 to the new Medical Management of Obstructive Sleep Apnea Syndrome Policy. • Added under Inclusion under unattended and attended home sleep study: History of stroke (more than 30 days previously), transient ischemic attack, coronary artery disease, or sustained supraventricular tachycardic or bradycardic arrhythmias inpatients who meet ONE of 6 criteria listed above • Removed under exclusions under unattended home sleep apnea test: History of Stroke. Added under exclusions under unattended home sleep apnea test: Idiopathic hypersomnia • Added under Inclusions children younger than 18 years of age: The initial study was inadequate, equivocal or non-diagnostic and the child's parents or caregiver report that the breathing patterns observed at home were different from those during testing. • Added codes 94762 and E0445 from policy Noninvasive Ear or Pulse Oximetry (replaced) as E/I. The topic was incorporated into this policy on 1/1/2020 but codes were not included. Rec'd inquiry

			from BCN CRC regarding this issue. • Minor editorial refinements – updated patients to individuals. • References added. • Policy statements unchanged. • Vendor: Carelon for BCBSM/internal team for BCN Post JUMP changes: • Policy title changed from Diagnosis of OSA Syndrome to Diagnosis of Sleep Disorders • This JUMP policy will not follow Carelon's classification of a child is 18 and younger but will maintain a child is younger than 18. • Policy Guidelines section moved to under Description/Background section. • Updated the below under Description/Background section under Significant Weight Change from 20% to 10% of body weight and removed 20kg to be in alignment with Carelon. • The purpose/intent of these updates are to align with Carelon and be consistent with our current JUP policy. • Under Exclusions/Contraindications to HSAT: dated Periodic limb disorder during sleep to Periodic limb movement disorder (PLMD) when one of the following are present: pregnancy, renal failure, iron deficiency anemia, peripheral neuropathy, use of antidepressant or antipsychotic medications, or continued hypersomnia and clinical symptoms of PLMD after sleep disordered breathing is ruled out by home sleep apnea testing to be in alignment with Carelon. • Under Exclusions/Contraindications to HSAT: Removed the below per

			JUMP committee recommendation: ○ History of seizures with use of anticonvulsants ○ Cardiac conditions ○ Restless leg syndrome • Under INITIAL ATTENDED (SUPERVISED) SLEEP STUDY PERFORMED IN A SLEEP LAB clarified section with Adults with suspected OSA. Added Adults with suspected sleep disorders other than OSA: • An in-lab supervised sleep study may be considered when there is suspicion of ANY of the following: ○ Central sleep apnea ○ Narcolepsy ○ Nocturnal seizures ○ Parasomnia ○ Idiopathic hypersomnia ○ Periodic limb movement disorder (PLMD)—to support a suspicion of PLMD in this context, ONE of the following must be documented: pregnancy, renal failure, iron deficiency anemia, peripheral neuropathy, use of antidepressant or antipsychotic medications, or continued hypersomnia and clinical symptoms of PLMD after sleep disordered breathing is ruled out by home sleep apnea testing ○ Nocturnal desaturation (due to severe COPD or certain restrictive thoracic disorders) ○ Any of the following conditions (right heart failure, polycythemia, cardiac arrhythmias during sleep, or pulmonary hypertension) when the etiology is unclear

			• Under REPEATED (ATTENDED) (SUPERVISED) SLEEP STUDY PERFORMED IN A SLEEP LAB: separated adults (18 years of age or older) and added the below children (younger than 18 years of age):
			  • Initial PSG is negative and a clinical suspicion of OSA remains
			  • Initial study was inadequate, equivocal or non-diagnostic and the child's parents or caregiver report that the breathing patterns observed at home were different from those during testing.
			  • A patient with established OSA continues to exhibit persistent snoring or other symptoms of sleep disordered breathing despite PAP adherence as defined by CMS criteria(use of PAP for at least 4 hours per night on 70% of nights during a consecutive 30-dayperiod)
			  • The patient has undergone adenotonsillectomy more than 8 weeks previously for management of established OSA
			  • To reevaluate the diagnosis of OSA and need for continued PAP if there is significant weight loss (defined as 10% of body weight) since the most recent sleep study
			  • To initiate or titrate CPAP or BPAP in a patient whose diagnostic study confirms that the patient is a candidate for positive airway pressure therapy and split-night study has not been performed or was inadequate:
			  ○ In pediatric individuals, an AHI greater than 1.5 is considered

			abnormal, and an AHI of 10 or more may be considered severe. • The initial sleep study has led to a diagnosis other than OSA and the repeat study is requested because of a change in clinical status or to assess efficacy after a change in therapy (ky)
1/1/24	10/17/23		• This policy is coming back to JUMP to change 95801 from E/I to Established. This will be in alignment with Carelon and our work with the project. This policy will go back to its original date for review in April of 2024. • Vendor: Carelon for BCBSM/internal team for BCN. (ky)
7/1/24	4/16/24		• Routine maintenance • References updated • Vendor: Carelon (ky)
1/1/25	10/15/24		• Routine maintenance • This policy is coming early for review and to update language to clarify that our intent aligns with Carelon. This policy will continue to come to October JUMP moving forward. • Updated Inclusions and Exclusions and MPS section language to clarify that our intent aligns with Carelon. • Vendor: Carelon Sleep Disorder Management 2024-10-20. (ky) Post JUMP: Per JUMP committee discussion removed the below under Repeat attended (supervised) sleep study performed in a sleep lab under both Individuals (18 years of age or older and younger than 18 years of age): o Initial PSG is negative and a clinical suspicion of OSA remains (ky)

Next Review Date: 4th Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 6/1/97	Revised: 6/28/01
BCBSM: 1/1/97	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: DIAGNOSIS OF SLEEP DISORDERS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, policy criteria apply.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.