

Sleep Management Solutions, Inc.
A CareCentrix Company

**2015 Criteria for Determining the Medical Necessity for the
Diagnosis and Treatment of Sleep Disordered Breathing in Adults and Children**

Date: 05/22/2015

Next Review Date: 05/22/2016

Policy Number: SLP012013

Clinical Guideline: Diagnosis and Treatment of Sleep Disordered Breathing in Adults and Children

This is a guideline only. The guideline does not represent medical advice. Medical decisions are the responsibility of the patient and the attending physician. Benefits are determined by the health plan and employer group contract and eligibility of the subscriber at the time services were rendered.

Sleep studies are performed to diagnose multiple types of sleep disorders, and to determine the effectiveness of treatments prescribed for patients who have been previously diagnosed with sleep disorders. Evaluation of signs and symptoms of obstructive sleep apnea should be conducted as part of routine health evaluations.

Signs and Symptoms of Sleep Disordered Breathing: Initial testing for the diagnosis of sleep disordered breathing is appropriate if a patient presents with at least one sign/symptom from category A and one from category B or 2 signs/symptoms from category B

- A. Evidence of Excessive Daytime Sleepiness
 - 1. Disturbed or restless sleep
 - 2. Non-Restorative sleep
 - 3. Frequent unexplained arousals from sleep
 - 4. Epworth Sleepiness Scale ≥ 10 (ESS)
- B. Evidence suggestive of Sleep Disordered Breathing
 - 1. Disruptive Snoring
 - 2. Witnessed apneas during sleep
 - 3. Choking or gasping during sleep
 - 4. BMI ≥ 30 ,
 - 5. Neck circumference $>/ 17$ in. (men) or $>/ 16$ in. (women)

Determining the Appropriate Site of Service for Sleep Testing

Sleep tests can be performed in an attended setting in a lab facility (hospital based or free standing) or out of sleep center using a portable monitoring device. Selection of the appropriate site of service for sleep testing requires evaluation of the following:

1. Medical necessity to perform sleep testing
 - a. Evaluation of the patient's clinical signs and symptoms
2. Evaluation of comorbid conditions
3. Evaluation of secondary sleep disorders
4. Cognitive and physical ability to safely and effectively perform the sleep test outside of the sleep laboratory

Home Sleep Test (HSAT) is an unattended study administered using a portable monitoring device that measures physiologic indicators of respiratory activity during sleep, unattended, in a setting outside of the sleep center facility for adult patients, age 18 years or older. The HSAT is indicated to diagnose obstructive sleep apnea, when there is a high clinical index of suspicion for obstructive sleep apnea.

An initial HSAT is medically necessary and appropriate when the **all of the following** conditions are met:

1. Signs/symptoms of obstructive sleep apnea are present
2. High pre-test probability of a diagnosis of obstructive sleep apnea
3. Absence of signs/symptoms of other sleep disorders or diagnoses, such as:
 - a. Periodic limb movement disorder (PLMD)
 - i. Greater than or equal to 15 periodic limb movements per hour resulting in arousal
 - b. Restless Leg Syndrome (RLS), which has been clinically documented
 - c. Parasomnias, including REM Behavior Disorder
 - d. Narcolepsy
 - e. Obesity hypoventilation syndrome
 - f. Central or treatment-emergent sleep apnea
 - i. Greater than 50% of the total apneas/hypopneas and central apneas/hypopneas greater than or equal to 5 times per hour. ⁽¹⁾
 - g. Nocturnal seizures occurring concomitantly with other suspected sleep disorders

4. Absence of clinical comorbidities that could degrade the accuracy of the HSAT, such as:
 - a. Moderate to severe pulmonary disease, such as COPD
 - b. Moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung disease, such as: kyphoscoliosis, myasthenia gravis, amyotrophic lateral sclerosis (ALS), post-polio syndrome, polymyositis, and Guillian Barre syndrome
 - c. Moderate to severe congestive heart failure (NYHA Class III or IV)
 - d. Obesity hypoventilation syndrome
 - e. Pulmonary hypertension
 - f. Cardiac arrhythmia(s)
5. Cognitive and physical ability to safely and effectively perform the sleep test outside of the sleep laboratory
6. Age 18 years or older.

Portable monitoring devices used in HSAT are categorized based on the number of channels measured; portable monitoring devices that measure fewer than 3 channels are not considered medically necessary for the diagnosis of sleep disorders.

Health Care Procedure Coding (HCPC) codes for HSAT:

G0398 - HSAT with type II portable monitor, unattended, minimum of 7 channels; EEG, EOG, EMG, ECG/heart rate, air flow, respiratory effort and oxygen saturation

G0399 - HSAT with type III portable monitor, unattended; minimum of 4 channels; 2 measuring respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen

G0400 - HSAT with type IV monitor, unattended; minimum of 3 channels

HSAT is also billed under Current Procedure Terminology (CPT) codes

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

95801 Sleep study, unattended, simultaneous recording; minimum of, heart rate, oxygen saturation, respiratory analysis (e.g. by airflow or peripheral arterial tone)

95806 Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)

Attended Sleep Study - Polysomnography (PSG)

Polysomnography is performed overnight, for at least 6 hours in a sleep laboratory facility, during which time the patient is continuously monitored, by a trained technologist directly observing the patient during the test. Parameters measured, at a minimum, are a frontal, central and occipital lead of electroencephalogram (EEG) a submental electromyogram (EMG) and a left and right electrooculogram (EOG) to allow sleep staging, extremity muscle and motor activity (EMG), as well as respiratory indicators such as ventilation, respiratory effort, and pulse oximetry.

Monitoring may include additional EEG or EMG channels, capnography or esophageal manometry, if clinically indicated. The patient is directly monitored throughout the sleep test, with continuous video and audio recording.

A facility-based PSG may be medically necessary when a patient presents with:

- Signs/symptoms of a sleep disorder, or
- When a patient previously diagnosed with obstructive sleep apnea requires sleep testing to measure the effectiveness of a current sleep therapy treatment plan, and **meets at least one of the following conditions:**
 1. Patient has a condition or comorbid diagnosis that may negatively impact the technical accuracy of a home sleep test; at least one of the following is present:
 - a. Moderate to severe pulmonary disease, such as COPD
 - b. Moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung disease, such as: kyphoscoliosis, myasthenia gravis, amyotrophic lateral sclerosis (ALS), post-polio syndrome, polymyositis, Guillian Barre syndrome
 - c. Moderate to severe congestive heart failure (NYHA Class III or IV)
 - d. Obesity hypoventilation syndrome
 - e. Pulmonary hypertension
 - f. Cardiac Arrhythmia(s)
 2. Suspicion of a secondary sleep disorder, other than obstructive sleep apnea, as evidenced by presence of at least one of the following:
 - a. Periodic limb movement disorder (PLMD)
 - i. Greater than or equal to 15 periodic limb movements per hour resulting in arousal
 - b. Restless Leg Syndrome (RLS), which has been clinically documented
 - c. Central or treatment-emergent sleep apnea

- i. Greater than 50% of the total apneas/hypopneas and central apneas/hypopneas greater than or equal to 5 times per hour. ⁽¹⁾
 - d. Obesity hypoventilation syndrome
 - e. Nocturnal seizures occurring concomitantly with other suspected sleep disorders
 - f. Narcolepsy
 - g. Parasomnias, including REM Behavior Disorder
3. The patient lacks the cognitive and physical ability to safely and effectively perform the sleep test outside of the sleep laboratory
4. Previous HSAT results technically inadequate or non-diagnostic in patients with a high pre-test probability for obstructive sleep apnea
5. Age 18 years or older

Facility Based Sleep Testing Codes

95805 – Multiple Sleep Latency Test (MSLT) or Maintenance of Wakefulness Test (MWT), recording, analysis and interpretation of physiological measurements of sleep during multiple trials. The MSLT is used to measure abnormal sleepiness during the patient's typical period of wakefulness. The MWT is used to measure wakefulness as an assessment of treatment of a sleep disorder.

95807 – Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate and oxygen saturation, attended by a technologist.

95808 – Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist

95810 – Polysomnography, sleep staging with 4 or more additional parameters of sleep, attended by a technologist.

95811 – Polysomnography; sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist.

95782 – Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist.

95783 – Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist.

A limited sleep study sometimes used for PAP desensitization and acclimatization (e.g., “PAP-Nap” study, CPT code 95807, modifier 52) is not medically necessary and is considered experimental, investigational or unproven.

Other Sleep Testing Codes

95803 – Actigraphy testing, recording, analysis, interpretation, and report (minimum 72 hours to 14 consecutive days).

In patients who are to undergo MSLT testing, actigraphy is a one-time covered service in lieu of paper or electronic sleep logs to evaluate sufficient sleep prior to MSLT testing. It is recommended that actigraphy be performed for at least 7 days to assure the validity of MSLT testing data. ⁽¹⁾ In evaluating the patient for obstructive sleep apnea, actigraphy is not medically necessary.

Overnight oximetry testing alone is not considered medically necessary for screening or as a diagnostic test for patients in whom obstructive sleep apnea is suspected.

Sleep testing (PSG or HSAT) is not considered medically necessary in patients with insomnia, circadian rhythm disorders, restless leg syndrome (RLS), unless symptoms are present with a concomitant sleep disorder (e.g., obstructive sleep apnea, narcolepsy, parasomnias).

Sleep testing (PSG or HSAT) is not considered medically necessary for screening asymptomatic patients.

Repeat Diagnostic Sleep Studies

A repeat PSG or HSAT for the diagnosis and treatment of sleep disorders is medically necessary and appropriate when at least **one of the following conditions is met**:

1. Initial testing results are inconclusive due to poor technical administration
 - a. If the initial test was a HSAT, and the results were inconclusive or negative, and there is still a high pre-test probability of obstructive sleep apnea, the repeat test may be a PSG.
2. Patient has had a significant change in weight that has impacted signs/symptoms of obstructive sleep apnea (e.g., a weight gain or loss of greater than or equal to 10% of total body weight.) and re-evaluation is warranted
3. Reassessment of clinical indicators of obstructive sleep apnea to determine the effectiveness of treatment with surgical intervention

- a. Tonsillectomy,
 - b. Adenoidectomy,
 - c. Uvulopalatoplasty (UPPP),
 - d. Maxillomandibular Advancement Surgery (MMA)
 - e. Other upper airway surgery
4. Implementation and evaluation of a fabricated oral mandibular advancement appliance by a qualified healthcare professional
- a. Treatment efficacy of an oral mandibular appliance may be assessed using HSAT
 - b. Adjustment of an oral mandibular appliance may be performed in the healthcare professional's office and then treatment efficacy may be assessed using HSAT, if medically necessary
 - c. An oral mandibular appliance may be adjusted manually during polysomnography to eliminate sleep disordered breathing in the sleep laboratory by a sleep technologist, and as prescribed by the qualified healthcare professional. The qualified healthcare professional may request in-facility polysomnography (CPT code 95810) for manual adjustment of the appliance, if medically necessary
 - d. PAP titration study (CPT code 95811) or split night sleep testing (CPT code 95811) is not correct coding for adjustment of an oral mandibular appliance
 - e. Over-the-counter, non-customized mandibular appliances are considered experimental, and are not medically necessary
5. HSAT testing may be administered over multiple nights, at the discretion of the ordering qualified healthcare professional, with the results aggregated into one single report. However, this is considered one diagnostic sleep test and should be coded as a single procedure.

Titration Studies for Positive Airway Pressure (PAP) therapy

Treatment of obstructive sleep apnea using PAP therapy requires that PAP pressure be titrated to the appropriate settings to achieve optimal therapeutic benefit. PAP pressure settings can be determined through an attended overnight, facility-based titration study, or through use of auto-titrating PAP (APAP) device, which automatically adjusts pressure based on the patient's physiological response during use outside of the sleep laboratory.

APAP titration, unattended, is medically necessary and appropriate when all of the following criteria are met:

1. Patient has been diagnosed with obstructive sleep apnea :

- a. Results of a PSG or HSAT indicate Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) of ≥ 15 events per hour, OR
 - b. AHI or RDI of ≥ 5 but < 15 , with clinical evidence of one of the following conditions:
 - i. Excessive daytime sleepiness
 - ii. Impaired cognition
 - iii. Mood disorders (e.g., depression, anxiety)
 - iv. Insomnia
 - v. Hypertension
 - vi. Ischemic heart disease
 - vii. History of stroke
2. Absence of comorbid condition that could impact the technical quality or sensitivity of the APAP in adjusting pressure to meet patient's needs
- a. Moderate to severe pulmonary disease, such as COPD
 - b. Moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung disease, such as: kyphoscoliosis, myasthenia gravis, amyotrophic lateral sclerosis (ALS), post-polio syndrome, polymyositis, Guillian Barre syndrome
 - c. Moderate to severe congestive heart failure (NYHA Class III or IV)
 - d. Obesity hypoventilation syndrome
 - e. Pulmonary hypertension
 - f. Cardiac arrhythmia(s)

Facility-based Titration studies can be conducted as a split night titration study or a full night titration study

Split Night Titration Study (CPT code 95811) is a sleep study that combines an initial diagnostic PSG followed by the initiation of PAP therapy. A split night study may be initiated as a diagnostic PSG (95810) and progress to split night titration when the patient demonstrates evidence of clinical severity of obstructive sleep apnea early during the study.

A split night titration study is medically necessary when all of the following criteria are met:

1. Patient exhibits signs and symptoms of obstructive sleep apnea
2. Patient meets criteria for facility based site of service for diagnostic sleep testing
3. After the PSG diagnostic test has been initiated, progression to PAP titration testing is appropriate if the patient meets the following criteria:
 - a) AHI or RDI ≥ 15 events per hour, or

b) AHI or RDI 5 events per hour with symptoms of obstructive sleep apnea, when obstructive sleep apnea is diagnosed within the first 2-3 hours of sleep testing (reference CMS). ⁽⁴⁾

In-Facility Polysomnography Positive Airway Pressure (PAP) Titration for adult patients (age 18 years or older) (CPT code 95811) is appropriate after an initial diagnostic sleep study (PSG or HSAT) has confirmed PAP therapy to be medically necessary, and the patient is not appropriate for unattended titration using auto-titrating PAP (APAP) device.

A full night, attended PAP titration study is medically necessary when the following conditions are met:

1. Patient has been previously diagnosed with significant obstructive sleep apnea
 - a. Results of a PSG or HSAT indicate AHI or RDI \geq 15 events per hour, OR AHI or RDI greater than or \geq 5 events per hour but less than 15 with clinical evidence of one of the following conditions:
 - i. Excessive daytime sleepiness
 - ii. Impaired cognition
 - iii. Mood disorders (e.g. depression, anxiety)
 - iv. Insomnia
 - v. Hypertension
 - vi. Ischemic heart disease
 - vii. History of stroke

AHI or RDI may be calculated based on at least two hours of continuous recorded sleep or, if calculated based on less than two hours of sleep, the total number of recorded events to calculate the AHI or RDI was, at a minimum the number of events that would have been required in a two-hour period.

EITHER OF THE FOLLOWING:

2. Patient has been diagnosed with a comorbid sleep disorder which would degrade the accuracy of out of sleep center APAP titration
 - a. Central sleep apnea or treatment-emergent sleep apnea
 - i. Central sleep apneas/hypopneas $>$ 50% of total apneas/hypopneas, or \geq 5 central apneas/hypopneas per hour diagnosed on previous PSG
 - ii. The presence of significant central sleep apnea or treatment-emergent sleep apnea may require the use of bi-level therapy or adaptive servo ventilation (ASV)
 - b. Periodic limb movement disorder

- i. Greater than or equal to 15 periodic limb movements per hour resulting in arousal
- b. Restless Leg Syndrome (RLS), which has been clinically documented
- c. Nocturnal seizures occurring concomitantly with other suspected sleep disorders
- d. Narcolepsy
- f. Parasomnias, including REM Behavior Disorder

OR

3. Comorbid medical conditions which would degrade the accuracy of APAP testing, such as:

- a. Moderate to severe pulmonary disease, such as COPD
- b. Moderate to severe neuromuscular/neurodegenerative disorder causing restrictive lung diseases, such as, kyphoscoliosis, myasthenia gravis, amyotrophic lateral sclerosis (ALS), post-polio syndrome, polymyositis, Guillian Barre syndrome
- c. Moderate to severe congestive heart (NYHA Class III or IV) failure
- d. Cardiac arrhythmia(s)
- e. Obesity hypoventilation syndrome
- f. Pulmonary hypertension

OR

4. Results of the initial diagnostic PSG or HSAT indicate significant oxygen desaturations during the study
- a. O₂ saturation < 80% for > 1% of recording time during a diagnostic home sleep test
 - b. O₂ saturation <80% for >1% of sleep time during a diagnostic facility based PSG
 - c. O₂ saturation <90% for >22% of recording time during a diagnostic home sleep test
 - d. O₂ saturation <90% for >30% of sleep time during a diagnostic facility based PSG

Multiple Sleep Latency Test (MSLT) (CPT code 95805)

MSLT is facility- based test used to objectively measure the ability or tendency to fall asleep during the patient's typical hours of wakefulness. This test is used to diagnose narcolepsy, or to provide a diagnosis of idiopathic hypersomnia, when other comorbid sleep disorders, including obstructive sleep apnea, have evaluated and/or treated.

Maintenance of Wakefulness Test (MWT) (CPT code 95805)

MWT is a facility- based test used to determine the ability to maintain wakefulness as an assessment of treatment of a sleep disorder. . This test is used to evaluate the patient’s response to treatment for sleep disorders, such as obstructive sleep apnea, narcolepsy or periodic limb movement disorder.

MWT testing is not considered to be medically necessary when required exclusively for employment, insurance or government license purposes.

The MSLT and MWT tests should be conducted using protocols established by the American Academy of Sleep Medicine (AASM). The MSLT should be performed when a patient is in a fully rested state, and not experiencing sleepiness due to inadequate prior sleep. For this reason, the MSLT is performed during the patient’s typical wake hours and always follows a PSG, during which the patient’s sleep status and adequacy are objectively measured. The MSLT should not be performed after a split night study (CPT code 95811).

To assure the accuracy of the MSLT, sufficient sleep must be documented prior to the MSLT. Sufficient sleep may be evaluated by the use of sleep logs (paper or electronic format) or actigraphy (CPT code 95803). Sleep data is typically collected for at least 7 days: ⁽¹⁾

Only the MWT (not MSLT) *may be performed* without a preceding PSG, at the discretion of the ordering healthcare professional.

The MSLT is medically necessary when the following criteria are met:

1. Patient exhibits documented symptoms of narcolepsy (one from each category)
 - a. Excessive daytime sleepiness – at least one of the following:
 - i. Epworth Sleepiness Scale / 10
 - ii. Recent history of routine unintentional naps or lapses into sleep during the day for > 30 days
 - b. Other recurrent symptoms of narcolepsy (one or more)
 - i. Cataplexy (sudden and transient loss of muscle tone, often triggered by emotions such as laughing or crying)
 - ii. Sleep paralysis
 - iii. Hypnagogic hallucinations
 - iv. Vivid dreams

Experimental and Investigational

The following diagnostic tests are considered experimental and investigational or unproven in members with symptoms suggestive of obstructive sleep apnea:

- a) Actigraphy testing when used alone to evaluate obstructive sleep apnea. Actigraphy, which consists of a small portable device that senses physical motion and stores the resulting information, has been used in research studies for the evaluation of rest-activity cycles. This technique, when used alone (single channel study), is not a validated method of diagnosing obstructive sleep apnea.
 1. Actigraphy testing (CPT code 95803) is recommended as a covered service to assess adequate sleep prior to MSLT testing. Actigraphy data is typically collected for 7 days (3 to 14 days) and billed as a single CPT code.
 - b) Acoustic pharyngometry, or SNAP testing with fewer than 3 channels
 - c) Cephalographic x-rays for diagnosis of obstructive sleep apnea. Lateral cephalographic x-rays and orthopantograms may be medically necessary for evaluating persons for oral appliances; lateral cephalographic x-rays may also be necessary to evaluate persons for obstructive sleep apnea surgery
 - d) X-rays of the temporomandibular joint or sella turcica
 - e) Laryngeal function studies
 - f) Sonography
 - g) Static charge sensitive bed
 - h) Tomographic x-ray
 - i) A limited sleep study sometimes used for PAP desensitization and acclimatization (e.g., “PAP-Nap” study, CPT code 95807, modifier 52)
 - j) Sleep Strip
 - k) Oral pressure therapy (e.g., Winx[®] Sleep Therapy System)
 - l) Provent[™] Professional Sleep Apnea Therapy Device
- B. Home sleep apnea testing (HSAT) in pediatric patients, younger than age 18 years, is not FDA-approved, and is therefore considered to be experimental and investigational.
- C. Sleep testing for screening of patients without symptoms or risk factors for a sleep disorder is not considered to be medically necessary.

Sleep Testing in Pediatric Patients (Younger than age 18 years)

Sleep disordered breathing in pediatric patients is evaluated when there is the presence of one or more of the following: ⁽¹⁾

1. Snoring
2. . Labored, paradoxical, or obstructed breathing during the child's sleep
3. 3. Sleepiness, hyperactivity, behavioral problems, or learning problems

IN-FACILITY POLYSOMNOGRAPHY (PSG) or PAP Titration - Pediatric (Younger than age 18 years)

Pediatric in-facility polysomnography (PSG) (CPT code 95782, 95808, 95810) is considered medically necessary for **ANY the following indications:**

- Obstructive sleep apnea suspected based on clinical assessment
- Following adenotonsillectomy in a child with mild preoperative obstructive sleep apnea with residual symptoms of obstructive sleep apnea
- Following adenotonsillectomy to assess for residual obstructive sleep apnea in child with preoperative evidence of moderate to severe obstructive sleep apnea,, obesity, craniofacial anomalies that obstruct the upper airway, or neurologic disorder (e.g., Down syndrome, Prader-Willi syndrome, myelomeningocele)
- Suspected congenital central alveolar hypoventilation syndrome or sleep related hypoventilation due to neuromuscular disorders or chest wall deformities
- Primary apnea of infancy
- Evidence of a sleep related breathing disorder in infant who has experienced an apparent life threatening event (ALTE)
- Child being considered for adenotonsillectomy to treat obstructive sleep apnea
- Assessment of response to treatment with an oral appliance
- Evaluation of child treated with mechanical ventilation for adjustment of ventilator settings.
- Evaluation prior to decannulation in child treated with tracheostomy for SRBD
- Clinical suspicion of an accompanying sleep related breathing disorder in a child with chronic asthma, cystic fibrosis, pulmonary hypertension, bronchopulmonary dysplasia, or chest wall abnormality (e.g., kyphoscoliosis)

Sleep disordered breathing in a pediatric patient is considered to be significant when the PSG demonstrates either of the following: ⁽¹⁾

1. AHI or RDI \geq 1
2. A pattern of obstructive hypoventilation, defined as at least 25% of total sleep time with hypercapnia ($\text{PaCO}_2 > 50$ mm Hg) in association with one or more of the following:

- a. Snoring.
- b. Flattening of the inspiratory nasal pressure waveform.
- c. Paradoxical thoracoabdominal motion.

Pediatric in-facility PAP titration (CPT code 95783, 95811) is considered medically necessary for ANY the following indications:

- Titration of positive airway pressure (PAP) in a child with obstructive sleep apnea
- Follow-up for child on chronic PAP support, to determine whether pressure requirements have changed due to growth and development; if symptoms recur while on PAP; or if additional or alternate treatment is instituted
- Noninvasive positive pressure ventilation (NIPPV) titration in child with other sleep-related breathing disorder

Adenotonsillectomy is considered to be the primary treatment for sleep disordered breathing in pediatric patients. However, PAP therapy may be considered when:

- Obstructive sleep apnea diagnosis established by PSG
- Adenotonsillectomy has been unsuccessful or is contraindicated, or when definitive surgery is indicated but must await complete dental and facial development

Treatment for Sleep Disorders with Positive Airway Pressure (PAP) Devices

Treatment for obstructive sleep apnea should be coordinated by a qualified healthcare professional who works with the patient to identify an appropriate treatment plan. It is expected that members receive lifestyle advice where applicable, for treatment of underlying factors contributing to the obstructive sleep apnea symptoms. Patients should be counseled in techniques to lose weight, stop smoking and/or decrease alcohol consumption.

Treatment of snoring alone, without significant obstructive sleep apnea, is *not* considered medically necessary.

Use of PAP therapy is considered medically necessary for members who are diagnosed with obstructive sleep apnea, as evidenced by a positive facility-based PSG, or a positive HSAT, as defined by *either* of the following criteria:

- A. AHI or RDI) $>/$ 15 events per hour
- B. AHI or RDI $>/5$ and $<$ 15 events per hour and at least one of the following is met:
 1. History of stroke;
 2. Hypertension
 3. Ischemic heart disease

4. Symptoms of impaired cognition, mood disorders or insomnia
5. Excessive daytime sleepiness

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

(A and B) or (A and C) satisfy the criteria in addition to the results of the sleep test:

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

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

B. PSG or HSAT demonstrates:

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

OR

C. PSG or HSAT demonstrates:

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

It should be noted, HSAT commonly underestimates the number of obstructive respiratory events per hour compared to in-laboratory polysomnography.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep. If the AHI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events used to calculate the AHI must be at least the number of events that would have been required in a 2-hour period (i.e., greater than or equal to 10 events).

The respiratory disturbance index (RDI) is equal to the episodes of apnea and hypopnea and respiratory-related arousals (RERAs) per hour.

$$\text{RDI} = (\text{RERAs} + \text{Hypopneas} + \text{Apneas}) \times 60 / \text{Total Sleep Time (in minutes)}$$

The American Academy of Sleep Medicine defines apnea 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 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least 4 percent oxygen desaturation. Only persons with an AHI or RDI, as defined in this policy that meets medical necessity criteria may qualify for PAP therapy.

Continuous Positive Airway Pressure (CPAP) at an effective pressure level is a standard treatment for obstructive sleep apnea. The appropriate pressure setting for CPAP may be determined during an attended facility titration study. A sleep technologist manually adjusts the CPAP pressure to determine the optimal therapeutic pressure setting, which is then programmed into the CPAP so that a fixed air flow pressure is consistently administered during therapy. ⁽¹¹⁾ Auto-Titrating Positive Airway Pressure (APAP) devices vary the pressure during treatment, based on measurements of the patient's physiologic response, such as air flow, pressure fluctuations or measures of airway resistance.

APAP devices may be used during an attended titration study to identify a single pressure for use with a standard CPAP for treatment of obstructive sleep apnea. More commonly, for patients without significant comorbidities (e.g., CHF, COPD, central or treatment-emergent sleep apnea, obesity hypoventilation syndrome, or other concomitant sleep disorders) APAP devices may be initiated in the home setting and used in the self-adjusting mode for treatment of patients with obstructive sleep apnea.

Clinical practice standards advise that patients being treated with fixed CPAP or APAP therapy have close clinical follow up to determine the effectiveness of treatment, especially during the initial weeks of therapy. If obstructive sleep apnea symptoms are not resolved effectively with CPAP or APAP, a re-evaluation, and possibly PAP titration study, may be indicated. ⁽¹⁰⁾

- Patients with obstructive sleep apnea who are intolerant of CPAP or APAP therapy, may be tried on bi-level therapy (BPAP) without a backup rate, after the qualified healthcare professional has documented that the patient has been tried on and failed CPAP therapy. Bi-level therapy delivers a higher inspiratory PAP pressure than expiratory PAP pressure, and may improve results and comfort for some patients.
- Bi-level therapy is also medically necessary for obstructive sleep apnea patients with concomitant breathing disorders, and for other diagnoses, including restrictive thoracic disorders, central or treatment-emergent sleep apnea, COPD and obesity hypoventilation syndrome. ⁽¹⁸⁾ Central sleep apnea is not explained by another central sleep apnea disorder (e.g., central sleep apnea with Cheyne Stokes breathing or due to a medication or substance) may also respond to bi-level therapy.

Bi-level therapy (BPAP) with a backup respiratory rate is considered medically necessary for restrictive thoracic disorders; severe COPD with evidence of hypercapnia, and hypoventilation syndromes after bi-level therapy without a backup rate has been tried and proven to be ineffective.

Bi-level therapy (BPAP) with a backup respiratory rate or Adaptive Servo-Ventilation (ASV) is considered medically necessary for the treatment of central or treatment-emergent sleep apnea when **all of the following criteria are met:**

- Diagnostic PSG shows 5 or more predominantly obstructive respiratory events (obstructive or mixed apneas, hypopneas or respiratory effort related arousals [RERAs]) per hour of sleep
- PSG during use of positive airway pressure without a backup rate shows significant resolution of obstructive events and emergence or persistence of central apneas or central hypopneas with all of the following:
 - Central apneas/ hypopneas \geq 5/hour
 - The number of central apneas/ hypopneas \geq 50% of total number of apneas/hypopneas

Adaptive Servo-Ventilation, autoSV/BiPAP and autoSV Advanced devices should not be used in patients with symptomatic chronic heart failure with reduced ejection fraction.

ResMed Ltd. identified a significant increase in the risk of cardiovascular death in patients with symptomatic, chronic heart failure (NYHA II – IV) with reduced ejection fraction (LVEF $</$ 45%) and moderate to severe predominant central sleep apnea (AHI $>/$ 15, CAHI/AHI $>/$ 50% and CAI $>/$ 10). ⁽²⁴⁾ Philips Respironics issued the same warning for at-risk patients using BiPAP autoSV/BiPAP autoSV Advanced devices. ⁽²⁵⁾

Treatment of obstructive sleep apnea with PAP therapy is dependent on patient adherence to the prescribed treatment. Close follow-up by a qualified healthcare professional is recommended during PAP treatment to assure that the patient is prescribed the appropriate therapeutic pressure and is fit with an appropriate mask in order to allow maximum use.

The first 90 days of PAP therapy are frequently considered an important trial period to assess patients' ability to comply with the treatment, and the overall efficacy of PAP in resolving and/or minimizing the obstructive sleep apnea symptoms. If PAP is considered inadequate, based on objective adherence monitoring and symptom evaluation, efforts should be implemented to improve PAP adherence, or alternative therapies should be considered. ⁽²⁾

PAP may be prescribed with expiratory pressure relief (e.g., C-Flex, C-Flex +, A-Flex, Bi-Flex) [Respironics, Inc., Murrysville, PA] to facilitate patient comfort and adherence.

When PAP therapy is not successful, evidenced by lack of patient adherence to prescribed therapy, and/or inadequate clinical response to therapy, the ordering qualified healthcare professional should discuss other treatment options with the patient.

PAP Adherence

PAP adherence is defined as use of PAP devices for 4 or more hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial use of the PAP device, reviewed by the treating physician. ⁽⁴⁾

Documentation of adherence to PAP therapy must be determined through direct download or visual inspection of usage data with written documentation provided in a report to be reviewed by the treating qualified healthcare professional and included in the patient's medical record. ⁽⁴⁾

In cases of lack of adherence, coverage of the PAP equipment and supplies may be discontinued based upon the health plan's coverage policy.

The following accessories and supplies are considered medically necessary for members who meet criteria for PAP therapy. Guidelines for use and frequency of replacement should be based on industry standard practice and medical necessity, and are acceptable to most patients with normal usage.

1. Chinstrap
2. Disposable and/or non-disposable filters
3. Nasal mask or oronasal mask (full face mask)
4. Headgear
5. Humidifier – heated or non-heated
6. Replacement cushion or nasal pillows for nasal application device
7. Replacement interface for oronasal mask
8. Tubing - heated or non-heated

PAP therapy remains the “gold standard” for treatment for obstructive sleep apnea. However, other non-surgical therapies may be considered when PAP cannot be tolerated or when an alternate therapeutic option is considered medically appropriate.

Coverage for oral appliances may be subject to the terms, conditions and limitations of the applicable benefit plan's External Prosthetic Appliances and Devices (EPA) or Durable Medical Equipment (DME) benefit and schedule of copayments.

A tongue-retaining device or a mandibular repositioning appliance (HCPCS codes E0485, E0486, S8262)), also referred to as mandibular advancement appliance or

mandibular advancement splint, as medically necessary for an individual with mild or moderate obstructive sleep apnea when EITHER of the following criteria is met:

- Apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) ≥ 15 but less than 30, as documented by polysomnography (PSG) or HSAT
- AHI or RDI ≥ 5 and < 15 as documented by PSG or HSAT, when accompanied by symptoms of obstructive sleep apnea (e.g., excessive daytime sleepiness, impaired cognition, mood disorders or insomnia) or when individual has hypertension, ischemic heart disease or history of stroke
- AHI or RDI ≥ 30 , in a patient who is unable to adhere to PAP therapy

The qualified healthcare professional must provide clinical documentation:

1. PAP therapy has been tried and failed
2. A tongue retaining device or mandibular repositioning device is medically necessary to treat obstructive sleep apnea

Over-the-counter (OTC) oral appliances obtained without a prescription are not considered medically necessary.

A tongue retaining device or mandibular repositioning device may be used in combination with PAP therapy, at the discretion of the qualified healthcare professional. This combined therapy typically allows PAP pressure to be reduced and often facilitates patient comfort and therapy adherence.

DEFINITIONS:

Actigraphy: measures physical activity, typically via a wrist-worn movement sensor, employed to estimate sleep and wakefulness based on relative levels of physical inactivity and activity. [1]

Apnea: cessation of airflow for at least ten seconds.

Apnea-Hypopnea Index (AHI): the total number of apneas and hypopneas per hour of sleep. AHI is an index of severity of obstructive sleep apnea. AHI is calculated by dividing the number of apneas plus the number of hypopneas by the number of hours of sleep.

Cataplexy: sudden attacks of muscle weakness and hypotonia triggered by an emotional stimulus such as laughter, anger or fear.

Central Sleep Apnea (CSA): the repeated cessation of breathing caused by the temporary signal loss from the brain sent to the breathing muscles. CSA is most often seen in patients with neurologic disorders, congestive heart failure and in patients who take certain medications (e.g., opiates, benzodiazepines).

Cheyne-Stokes Respirations: a type of central sleep apnea seen in patients with congestive heart failure.

Electroencephalography (EEG): evaluates brain waves during different stages of sleep.

Electrocardiography (EKG/ECG): measures electrical rhythm of the heart.

Electromyography (EMG): evaluates muscle movement during sleep.

Electrooculography (EOG): evaluates eye movement during dream (REM) sleep.

Home Sleep Apnea Test (HSAT): also known as portable or unattended sleep test. HAST is conducted in the home setting or in a facility outside of the sleep laboratory. This test is unattended by a sleep technologist and may provide many of the same measurements as an in-lab sleep study, such as brain waves, heart rate, breathing, sleep position and oxygen saturation. This test is used to diagnose OSA in patients without comorbid conditions.

Hypersomnolence: excessive sleepiness during the typical period of wakefulness.

Hypnagogic Hallucinations: vivid, dream-like experiences occurring at sleep onset.

Hypnopompic Hallucinations: vivid, dream-like experiences occurring just before or during awakening.

Hypopnea: an abnormal respiratory event lasting at least ten seconds with at least 30% reduction in thoracoabdominal movement or airflow as compared to baseline and with at least a 4% oxygen desaturation [1].

Insomnia: an inability to sleep; abnormal wakefulness which may be characterized as difficulty falling asleep or sustained awakenings from sleep.

Maintenance of Wakefulness Test (MWT): measures sleep latency when the patient is instructed to attempt to remain awake in an unstimulated environment. MWT measures wakefulness during a person's typical wake period. It is used to assess a person's response to therapy (wakefulness) when treatment for a sleep disorder (e.g., OSA, PLMD, narcolepsy, etc.) has been undertaken (e.g., PAP, pharmacotherapy, etc.).

Multiple Sleep Latency Test (MSLT): measures how quickly the patient falls asleep when instructed to relax in a quiet and dimly lit room. MSLT is performed to assess pathologic sleepiness during the patient's typical wake period.

Myoclonus: abnormal contraction of muscles which can prevent restful sleep.

Narcolepsy: recurrent, uncontrollable episodes of sleep often associated with hypnogogic hallucinations, sleep paralysis and cataplexy. Patients experience profound daytime sleepiness.

Nocturnal: pertaining to, occurring at, or active at night.

O2 Saturation: percentage of oxygen carried by the blood.

Obstructive Sleep Apnea (OSA): characterized by repetitive apneas and/or hypopneas during sleep, caused by complete or partial collapse of the pharyngeal airway during sleep. In adults, an apnea/hypopnea index (AHI) greater than or equal to 5 but less 15, is considered mild OSA. AHI greater than or equal to 15 but less than 30 is considered moderate OSA. AHI greater than or equal to 30 is considered severe OSA. In pediatric patients, an AHI greater than or equal to 1 is considered abnormal.

PAP-NAP: limited sleep study during which sleep technologists provide behavioral coaching and PAP therapy desensitization to sleep patients.

Parasomnias: abnormal sleep behaviors during sleep, such as sleep walking, sleep talking, sleep eating, sleep terrors, dream enactment.

Periodic Limb Movement Disorder (PLMD): characterized by an involuntary, repetitive limb movement that may occur during sleep and usually involve the legs. This causes frequent arousals from sleep and often results in excessive daytime sleepiness.

Polysomnography: test performed in the sleep laboratory to evaluate the parameters of sleep.

REM Behavior Disorder: parasomnia occurring in REM sleep that primarily affects men of middle age or older with a history of cerebrovascular disease. Presenting symptoms include violent behavior during sleep and dream enactment, typically with memory of the event.

Respiratory Disturbance Index (RDI): number of apneas + hypopneas + respiratory-related events during the night divided by the total number of hours slept.

Restless Leg Syndrome (RLS): unpleasant discomfort typically inside the calves when sitting or lying down, especially just before sleep. This produces an irresistible

urge to move the legs and may interfere with the ability to fall asleep. Other extremities or other body parts may also be affected [2].

Seizure: a paroxysmal event resulting from a sudden excessive discharge of the neurons of the cerebral cortex. Lack of sleep facilitates epileptic activity and seizures [1].

Sleep Bruxism: is an involuntary grinding of the teeth during sleep.

Sleep Enuresis: bedwetting.

Sleep Paralysis: experience of being awake but unable to move and lasting a few seconds. By itself, sleep paralysis may be a normal phenomenon. However, when present with other symptoms, it may be a part of the symptomatology of narcolepsy [2].

Sleep Terrors: similar to nightmares, but occurring in non-REM sleep. The patient may enact the nightmare without memory of the event.

Snoring: noisy breathing occurring during sleep due to vibration of the uvula and soft palate

Somnambulism: sleepwalking; rising out of bed and walking during non-REM sleep, usually occurring in the first third of the night.

Somniloquy: the act of talking during non-REM sleep.

Split-Night Sleep Study: the initial diagnostic portion of polysomnography followed by PAP titration therapy occurring during the same sleep test.

Treatment-Emergent Central Sleep Apnea: previously known as complex sleep apnea; persistence or emergence of central apneas and hypopneas during the initiation of PAP therapy without a backup respiratory rate for OSA, despite significant resolution of obstructive respiratory events. [1]

Type I Sleep Study Devices: for sleep studies performed attended in a sleep laboratory. Minimum requirements include recording of EEG, EOG, chin EMG, anterior tibialis EMG, ECG, airflow, respiratory effort and oxygen saturation. Body position is documented. The sleep technologist is in attendance during Type I sleep studies [2].

Type II Sleep Study Devices: for sleep studies performed unattended outside of a sleep laboratory. Type II devices are portable devices that have a minimum of seven channels (e.g. EEG, EOG, EMG, ECG or heart rate, airflow, respiratory effort and oxygen saturation and monitor sleep staging). The sleep technologist is not in attendance during Type II sleep studies [2].

Type III Sleep study Devices: for sleep studies performed unattended outside of a sleep laboratory. Type III devices are portable devices that monitor and record a minimum of four channels and must record airflow, heart rate or ECG and oxygen saturation. The sleep technologist is not in attendance during Type III sleep studies [2].

Type IV Sleep Study Devices: for sleep studies performed unattended outside of a sleep laboratory. Type IV devices are portable devices that monitor and record a minimum of three channels and must record airflow as one of the required channels. Other measurements may include oximetry and heart rate. The sleep technologist is not in attendance during Type IV sleep studies [2].

[1] International **Classification of Sleep Disorders – Third Edition (ICSD-3)**, American Academy of Sleep Medicine; 2014

[2] Florida Blue Clinical Guidelines; 2015

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GUIDELINE UPDATE INFORMATION:

12/19/2013	New coverage guideline
5/22/2015	Scheduled review. Adherence criteria, criteria related to Adaptive Servo Ventilation and definitions added. Experimental/Investigational diagnostic tests updated: Actigraphy used alone, and use of Acoustic pharyngometry, or SNAP testing with fewer than 3 channels. Guideline reformatted, references updated