Sleep Disorder Management
Diagnostic & Treatment Guidelines

Program Guidelines
Effective Date: January 1, 2016

Proprietary
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AIM Specialty Health (AIM) has developed proprietary diagnostic and treatment management clinical guidelines (together with any updates, referred to collectively as the “Guidelines”). The Guidelines are designed to evaluate and direct the appropriate management of sleep diagnostic testing and treatment scenarios. They are based on data from the peer-reviewed scientific literature, from criteria developed by specialty societies and from guidelines adopted by other health care organizations. Access to these guidelines is being provided for informational
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Commented [D1]: a. They contraindicated this statement by their overly restrictive proof of compliance. I changed those sections to jive with Medicare’s compliance. Coverage issues that affect DME providers need to be reviewed and altered. I will comments on the demand for unpaid clinical and administrative services. b. Paragraph 3 claims that the clinician’s judgment supersedes the guidelines however, they need to state that some orders deemed relevant by the clinician may not be covered.
Polysomnography and Home Sleep Testing

CPT and HCPCS Codes

95782.................. Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95783.................. Polysomnography; younger than 6 years, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95800.................. Sleep study, unattended simultaneous recording heart rate, oxygen saturation, respiratory analysis (e.g., by airflow or peripheral arterial tone), and sleep time
95801.................. Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation and respiratory analysis (e.g., by airflow or peripheral arterial tone)
95806.................. Sleep study, unattended, simultaneous recording of heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)
95807.................. Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist
95808.................. Polysomnography; Any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810.................. Polysomnography; Age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist
95811 .................. Polysomnography; Age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
G0398 ................. Home sleep study with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation
G0399 ................. Home sleep study with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400 ................. Home sleep study with type IV portable monitor, unattended; minimum of 3 channels

Scope of the Guideline

This guideline is applicable to performance of lab based sleep studies (polysomnography) and home based sleep studies for the following disorders

- Obstructive sleep apnea (OSA) - the most common of the sleep disorders.
- Central sleep apnea (CSA)
- Narcolepsy
- Parasomnias and related sleep movement disorders including:
  o Confusion arousals
  o Somnambulism (sleepwalking)
  o Sleep terrors
  o Rapid eye movement (REM) sleep behavior disorder
  o Sleep-related epilepsy
  o Sleep bruxism
  o Sleep enuresis (bed wetting)
  o Periodic limb movement disorder (PLMD)
- Nocturnal oxygen desaturation

Overview

Obstructive sleep apnea (OSA) is a common disorder affecting up to 2–4% of the population. Many patients with OSA remain undiagnosed. OSA is characterized by repeated interruption of breathing during sleep (apnea) or by episodes of diminished airflow to the lungs (hypopnea). These episodes are the result of narrowing or closure of the upper airway during sleep. The clinical hallmarks of OSA are reported loud snoring or apnea during sleep (if the patient has a bed partner), or patient complaints of frequent awakenings with gasping or choking. This fragmentation of sleep leads to daytime sleepiness and other
For patients requiring treatment with CPAP or BPAP, pressure levels need to be titrated to each patient’s particular needs. For patients whose diagnostic sleep study is performed in a lab setting, it may be possible to diagnose OSA and perform the positive airway pressure (PAP), resulting in pneumatic splinting of the airway, is the mainstay of treatment of OSA. The pressure provided throughout the respiratory cycle may be constant (CPAP) or may vary between inspiration and expiration (bi-level CPAP or BPAP). Automatically titrating positive airway pressure (APAP) supplies variable pressure in response to changes in various parameters e.g., sleeping position, sleep stage or changes in body habitus. Although some patients may prefer APAP or BPAP to CPAP, use of APAP or BPAP has not increased compliance with therapy.

Treatment of OSA: Positive airway pressure (PAP), resulting in pneumatic splinting of the airway, is the mainstay of treatment of OSA. The pressure provided throughout the respiratory cycle may be constant (CPAP) or may vary between inspiration and expiration (bi-level CPAP or BPAP). Automatically titrating positive airway pressure (APAP) supplies variable pressure in response to changes in various parameters e.g., sleeping position, sleep stage or changes in body habitus. Although some patients may prefer APAP or BPAP to CPAP, use of APAP or BPAP has not increased compliance with therapy.

The severity of OSA is graded as follows in adult (age 19 years or older) patients:

Mild OSA: AHI = 5–14
Moderate OSA: AHI = 15–30
Severe OSA: AHI = greater than 30

The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness, and AHI greater than 15 is considered severe.

Diagnosis of OSA: Although OSA may be suspected based on the symptoms described above, physical exam findings (e.g., obesity, increased neck circumference, retrognathia etc.), or presence of comorbidities, the diagnosis must be confirmed by a sleep test. During sleep testing, various physiological parameters are monitored while the patient sleeps. Sleep testing may be performed at a hospital, a freestanding sleep lab or at the patient’s home.

Sleep testing may be classified as follows:

Type I................. An attended sleep study performed in a hospital or freestanding sleep lab with continuous and simultaneous monitoring of electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (EKG), electromyogram (EMG), oxygen saturation, respiratory effort, and airflow. Type I studies are also known as polysomnography (PSG).

Type II................. A sleep study (usually unattended) performed with portable equipment with continuous and simultaneous monitoring of EEG, EOG, EKG, EMG, oxygen saturation, respiratory effort, and airflow. Type II studies are similar to type I (PSG) studies except that the former are usually performed in the home.

Type III.............. An unattended sleep study performed with portable equipment with monitoring of a minimum of four channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation. The studies are performed in the home and differ from types I and II in that they do not provide data on sleep staging.

Type IV.............. An unattended sleep study performed with portable equipment with monitoring of three or fewer physiological parameters only one of which is airflow. The studies are performed in the home and differ from types I and II in that they do not provide data on sleep staging.

Home sleep studies offer an alternative to PSG for some patients with suspected OSA. This option is more comfortable and convenient for the patient, is less costly and more readily available in regions where the demand for PSG is high. Multiple night home sleep studies may be indicated in some situations. Type I attended sleep studies may be indicated in some situations. Patients who are 18 years old or less and those with severe chronic obstructive pulmonary disease (COPD), advanced congestive heart failure (CHF), neuromuscular diseases and/or cognitive impairment are not suitable candidates for home sleep studies. Patients with sleep disorders other than OSA are not suitable candidates for home sleep testing.

Regardless of the site of testing, sleep studies objectively measure the degree of respiratory disturbance during sleep. Episodes of apnea (cessation of breathing lasting at least 10 seconds and hypopnea (reduction, but not a cessation of air exchange, with an associated fall in oxygen saturation [at least 3 to 4%] or arousal) are recorded. The apnea/hypopnea index (AHI) is the average number of apneic and hypopneic episodes per hour based on a minimum of two hours of recording. The respiratory disturbance index (RDI), a similar (but not identical) parameter, is the average number of apneas, hypopneas and respiratory effort related arousals (RERAS) per hour based on at least two hours of recording. For the purposes of this guideline the terms AHI and RDI can be used interchangeably.

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Although OSA may occur in all age groups, it is most common in patients between 40 and 70 years old. The incidence of OSA in obese patients is considerably higher than in non-obese individuals. 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). Because of daytime sleepiness, deaths related to motor vehicle accidents are also more common in patients with OSA.

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Treatment of OSA: Positive airway pressure (PAP), resulting in pneumatic splinting of the airway, is the mainstay of treatment of OSA. The pressure provided throughout the respiratory cycle may be constant (CPAP) or may vary between inspiration and expiration (bi-level CPAP or BPAP). Automatically titrating positive airway pressure (APAP) supplies variable pressure in response to changes in various parameters e.g., sleeping position, sleep stage or changes in body habitus. Although some patients may prefer APAP or BPAP to CPAP, use of APAP or BPAP has not increased compliance with therapy.

For patients requiring treatment with CPAP or BPAP, pressure levels need to be titrated to each patient’s particular needs. For patients whose diagnostic sleep study is performed in a lab setting, it may be possible to diagnose OSA and perform the

Diagnosis of OSA: Although OSA may be suspected based on the symptoms described above, physical exam findings (e.g., obesity, increased neck circumference, retrognathia etc.), or presence of comorbidities, the diagnosis must be confirmed by a sleep test. During sleep testing, various physiological parameters are monitored while the patient sleeps. Sleep testing may be performed at a hospital, a freestanding sleep lab or at the patient’s home.

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For patients requiring treatment with CPAP or BPAP, pressure levels need to be titrated to each patient’s particular needs. For patients whose diagnostic sleep study is performed in a lab setting, it may be possible to diagnose OSA and perform the
titration study in a single night. This approach, known as split-night study, may be used when AHI exceeds 20 per hour based on the first 2 hours of testing. Those who do not meet criteria for split-night protocol require either a second overnight titration study or temporary use of APAP as a means of titrating CPAP. Titration is not required if APAP is selected as the long-term therapeutic approach. Oral appliances (OA) which include mandibular repositioning appliances (MRA) and tongue retaining devices (TRD) may be used in appropriately selected patients. Other treatments for OSA (not addressed in this guideline) include positional therapy, non-surgical weight loss measures, or bariatric surgery. Surgical approaches to modification of the upper airway are usually reserved for those patients who have not responded to or tolerated other therapies. Tracheostomy should be considered when other measures fail and OSA is deemed severe enough to warrant this procedure. Adenotonsillectomy is the preferred initial approach to treatment of OSA in children. CPAP is reserved for those children who have an inadequate response to surgery, do not have enlarged tonsils or are not good surgical candidates.

In the management of patients with OSA, long-term compliance with positive airway pressure devices remains problematic. Adherence to therapy is defined by the Centers for Medicare & Medicaid Services (CMS) as use of PAP for greater than or equal to 4 hours per night on 70% of nights during a consecutive thirty (30) day period. Compliance may be as low as 50% at one year and for this reason compliance monitoring is an important component of the management of patients with OSA. Every effort should be made to achieve compliance. Newer PAP devices record (and may transmit) use times such that compliance monitoring may be performed remotely. Unless compliance is achieved and documented, the continued use of PAP devices (and the ongoing provision of associated supplies) cannot be considered to be medically necessary.

### Indications For Home (Unattended) Sleep Studies

**Note:** Home sleep studies performed with Type II and Type III devices (as defined above) are considered medically necessary when the criteria below are met. Type IV devices are considered to be not medically necessary in all clinical scenarios.

#### Suspected OSA:

Home sleep studies are indicated if the patient meets any of the following criteria (1–3) AND has no contraindication to a home sleep study as outlined in table 1 below:

1. Observed apneas during sleep; OR
2. A combination of at least two (2) of the following (a–e):
   a. Excessive daytime sleepiness evidenced by an Epworth sleepiness scale score greater than 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;
   b. Habitual snoring, or gasping/choking episodes associated with awakenings;
   c. Treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications);
   d. Obesity, defined as a body mass index greater than 30 kg/m² or increased neck circumference defined as greater than 17 inches in men or greater than 16 inches in women;
   e. Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease; OR
3. History of stroke (greater than 30 days previously) transient ischemic attack, coronary artery disease, or sustained supraventricular tachycardic or bradyarrhythmic arrhythmias in patients who meet one of the criteria in 2a–e above.

#### Established OSA - follow-up home sleep studies:

A patient with established diagnosis of OSA should have a follow-up home sleep study if either of the following applies AND there is no contraindication to a home sleep study as outlined in table 1 below:

1. To assess efficacy of surgery (including adenotonsillectomy or upper airway) or oral appliances/devices; OR
2. To re-evaluate 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.
Table 1: Contraindications to Home Sleep Study

<table>
<thead>
<tr>
<th>Contraindications</th>
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</thead>
<tbody>
<tr>
<td>1. Patient is 18 years old or younger</td>
</tr>
<tr>
<td>2. Moderate or severe chronic obstructive pulmonary disease (COPD) – 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</td>
</tr>
<tr>
<td>3. Moderate or severe congestive heart failure (CHF) – New York Heart Association (NYHA) class III or IV</td>
</tr>
<tr>
<td>4. CHF with a history of ventricular fibrillation or sustained ventricular tachycardia in a patient who does not have an implanted defibrillator</td>
</tr>
<tr>
<td>5. Cognitive impairment (inability to follow simple instructions) resulting in inability to apply the home sleep testing equipment when another individual is not available to assist with this task</td>
</tr>
<tr>
<td>6. Physical impairment resulting in inability to apply the home sleep testing equipment when another individual is not available to assist with this task</td>
</tr>
<tr>
<td>7. The patient has a suspected or established diagnosis of one of the following conditions: (a) Central Sleep Apnea, (b) Periodic Limb Movement Disorder, (c) Narcolepsy, (d) Idiopathic Hypersomnia, (e) Parasomnia, (f) Nocturnal Seizures</td>
</tr>
<tr>
<td>8. Previous technically suboptimal home sleep study (2 nights of study attempted)</td>
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<tr>
<td>9. Previous 2-night home sleep study which did not diagnose OSA in a patient with ongoing clinical suspicion of OSA</td>
</tr>
<tr>
<td>10. Patient is oxygen dependent for any reason</td>
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<tr>
<td>11. History of cerebrovascular accident (CVA) within the preceding 30 days</td>
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<tr>
<td>12. Chronic opiate narcotic use; when discontinuation is not an option. Diagnostic sleep testing for patients using opiate narcotics for acute self-limited conditions, should ideally be deferred until the medications have been stopped</td>
</tr>
<tr>
<td>13. Body Mass Index (BMI) &gt; 33 and elevated serum bicarbonate level (&gt;28 mmol/L)</td>
</tr>
<tr>
<td>14. Established diagnosis of obesity hypoventilation syndrome</td>
</tr>
</tbody>
</table>

Indications For In-Lab (Attended) Sleep Studies In Adult Patients (Age 19 Years or Older)

Suspected OSA (in patients with unspecified sleep apnea and nocturnal desaturation, OSA should be suspected and excluded if clinically appropriate):

An in-lab sleep (attended) study is indicated if the patient meets any of the following criteria (1–3) AND has a contraindication to a home sleep study (as listed in table 1 above):

1. Observed apneas during sleep; OR
2. A combination of at least two (2) of the following (a–e):
   a. Excessive daytime sleepiness evidenced by an Epworth sleepiness scale score greater than ten (10), inappropriate daytime nappling (e.g., during driving, conversation, or eating), or sleepiness that interferes with daily activities and is not explained by other conditions;
   b. Habitual snoring or gasping/choking episodes associated with awakenings;
   c. Treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications);
   d. Obesity, defined as a body mass index greater than 30 kg/m² or increased neck circumference defined as greater than seventeen (17) inches in men or greater than sixteen (16) inches in women;
   e. Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease; OR
3. History of stroke, transient ischemic attack, coronary artery disease, or sustained tachycardic or bradycardic arrhythmias in patients who meet one of the criteria in 2a–e above.
Suspected sleep disorder other than OSA
An in-lab supervised sleep study is appropriate when there is suspicion of any of the following (1–7):

1. Central sleep apnea
2. Narcolepsy
3. Nocturnal seizures
4. Parasomnias
5. Idiopathic hypersomnia
6. Periodic limb movement disorder
7. Nocturnal desaturation (due to severe COPD or certain restrictive thoracic disorders) or unexplained right heart failure, polycythemia, cardiac arrhythmias during sleep or pulmonary hypertension

Established sleep disorder (OSA or other): follow-up laboratory studies:
A patient with established diagnosis of OSA or other sleeping disorders should have a follow-up in-lab sleep study if either of the following (1 or 2) applies AND the patient has a contraindication to a home sleep study (as listed in table 1 above):

1. To assess efficacy of surgery (including adenotonsillectomy or upper airway) or oral appliances/devices; OR
2. To re-evaluate 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

A patient with established diagnosis of OSA or other sleeping disorders should have a follow-up in-lab study if any of the following (1–3) applies

1. To titrate CPAP/BPAP in a patient who has a contraindication to the use of APAP (e.g., CHF, COPD) or for whom an attempt at APAP titration has been unsuccessful; OR
2. To titrate CPAP/BPAP in a patient with a contraindication to the use of APAP (e.g., CHF, COPD) whose attempted split-night study did not adequately establish appropriate CPAP/BPAP treatment parameters; OR
3. To re-titrate CPAP/BPAP in a patient who has a contraindication to APAP (e.g., CHF, COPD) and has recurrence of symptoms or worsening of symptoms during treatment with CPAP/BPAP.

Indications for In-Lab (Attended) Sleep Studies in Non-Adult Patients (Age 18 Years or Younger)

Suspected sleep disorder (OSA or other)
An in-lab sleep (attended) study is indicated if the patient meets any of the following criteria 1–11 below:

1. Habitual snoring in association with one or more of criteria a–e below:
   a. Restless or disturbed sleep
   b. Behavioral disturbance or learning disorders including deterioration in academic performance, attention deficit disorder, hyperactivity
   c. Frequent awakenings
   d. Enuresis (bedwetting)
   e. Growth retardation or failure to thrive; OR
2. Excessive daytime somnolence or altered mental status not explained by other conditions; OR
3. Polycythemia not explained by other conditions; OR
4. Cor pulmonale not explained by other conditions; OR
5. Witnessed apnea with duration greater than two (2) respiratory cycles; OR
6. Labored breathing during sleep; OR
7. Hypertrophy of the tonsils or adenoids in patients at significant surgical risk such that the exclusion of OSA would allow avoidance of surgery; OR

8. Suspected congenital central alveolar hypoventilation syndrome or sleep-related hypoventilation due to neuromuscular disease or chest wall deformities; OR

9. Clinical evidence of a sleep-related breathing disorder in infants who have experienced an apparent life-threatening event; OR

10. For exclusion of OSA in a patient who has undergone adenotonsillectomy for suspected OSA more than eight (8) weeks previously; OR

11. 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.

**Established Sleep Disorder (OSA or other) – follow up studies**

A follow-up in-lab sleep study is appropriate in any of the following (1–5) situations:

1. A patient with established OSA continues to exhibit persistent snoring or other symptoms of sleep disordered breathing despite treatment with positive airway pressure therapy; OR

2. The patient has undergone adenotonsillectomy more than eight (8) weeks previously for management of established OSA; OR

3. To re-evaluate 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; OR

4. To 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; OR

5. 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.

**Bibliography**

**Specialty Society Guidelines and Systematic Reviews**


Other Literature


Multiple Sleep Latency Testing (MSLT) and Maintenance of Wakefulness Testing (MWT)

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

Scope of the Guideline
This guideline is applicable to performance of Multiple Sleep Latency Testing (MSLT) or Maintenance of Wakefulness Testing (MWT) in the evaluation of narcolepsy or idiopathic hypersomnia.

Overview

Narcolepsy:
Compared to obstructive sleep apnea (OSA), which affects 2 to 4% of the population, narcolepsy is a rare disease affecting 0.025 to 0.05%. Narcolepsy is a disorder characterized by excessive daytime sleepiness, often associated with cataplexy, hypnagogic hallucinations, sleep paralysis or any combination of these symptoms. The excessive sleepiness of narcolepsy is characterized by repeated episodes of naps or lapses into sleep of short duration (usually less than one hour). The diagnosis of narcolepsy is usually confirmed by an overnight polysomnography (PSG) followed by MSLT. If the PSG shows evidence of OSA, this diagnosis should be treated before pursuing a diagnosis of narcolepsy.

Idiopathic hypersomnia:
Daytime sleepiness following adequate (or even prolonged) nocturnal sleep duration and non-refreshing daytime naps are characteristic of idiopathic hypersomnia. Patients with idiopathic hypersomnia may have sleep paralysis and hallucination but cataplexy is absent. Despite prolonged sleep duration patients with idiopathic hypersomnia display difficult morning awakening, sleep drunkenness and constant somnolence. Idiopathic hypersomnia is rarer than narcolepsy and tends to be more resistant to treatment. A diagnosis of idiopathic hypersomnia requires exclusion of other causes of fatigue and hypersomnolence including hypothyroidism, depression, obstructive sleep apnea etc.

Multiple sleep latency testing (MSLT):
During MSLT the patient is provided several opportunities to nap. Physiologic parameters recorded include electroencephalography (EEG), electrooculography (EOG), mental or submental electromyography (EMG), and electrocardiography (ECG). The sleep latency (time to onset of sleep), and the presence of sleep onset rapid eye movement (SOREM) events are evaluated. Initial MSLT occasionally fails to identify narcolepsy. Repeat testing may be necessary when the initial results are negative or ambiguous and the clinical history indicates a diagnosis of narcolepsy. MSLT should not be performed while the patient is taking (or within two weeks of stopping) stimulant medications, sedatives or rapid eye movement (REM) suppressing medications

Maintenance of wakefulness testing (MWT):
Measures the ability to stay awake for a defined period of time. The test is performed in the sleep laboratory in environment conducive to sleep. MWT should not be performed while the patient is taking (or within two weeks of stopping) stimulant medications, sedatives or rapid eye movement (REM) suppressing medications
Indications for MSLT and/or MWT

Initial MSLT and/or MWT is appropriate for suspected narcolepsy when all of the following conditions are met

a. Daytime hypersomnolence has been present for at least eight weeks
b. The patient has at least one of the following
   i. Disrupted nocturnal sleep
   ii. Cataplexy
   iii. Hallucinations (hypnagogic or hypnopompic)
   iv. Sleep paralysis
   v. The patient has undergone polysomnography since the onset of symptoms (PSG) and symptoms persist despite adequate treatment of obstructive sleep apnea (if present)

Repeat MSLT and/or MWT is appropriate for suspected narcolepsy when all of the following conditions are met

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

MSLT and/or MWT is appropriate for idiopathic hypersomnia when all of the following conditions are met

a. Daytime hypersomnolence has been present for at least eight weeks
b. The patient has at least one of the following
   i. Difficult morning awakening
   ii. Prolonged night sleep
   iii. Sleep drunkenness
   iv. Frequent non-refreshing daytime naps
   v. The patient has undergone polysomnography since the onset of symptoms (PSG) and symptoms persist despite adequate treatment of obstructive sleep apnea (if present)

Bibliography

Specialty Society Guidelines and Systematic Reviews


Other Literature

Management of Obstructive Sleep Apnea (OSA) using Auto-Titrating Positive Airway Pressure (APAP) and Continuous Positive Airway Pressure (CPAP) Devices

CPT and HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>E0561</td>
<td>Humidifier, non-heated, used with positive airway pressure device</td>
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<tr>
<td>E0562</td>
<td>Humidifier, heated, used with positive airway pressure device</td>
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<tr>
<td>E0601</td>
<td>Single level continuous positive airway pressure device or auto-titrating continuous positive airway pressure</td>
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<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<td>A4604</td>
<td>Tubing with heating element</td>
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<td>A7027</td>
<td>Combination Oral/Nasal Mask used with positive airway pressure device, each</td>
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<td>A7028</td>
<td>Oral Cushion, Replacement for Combination Oral/Nasal Mask, each</td>
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<td>A7029</td>
<td>Nasal Pillows, Replacement for Combination Oral/Nasal Mask, pair</td>
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<td>Full Face Mask used with positive airway pressure device, each</td>
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<td>Face Mask Cushion, Replacement for Full Face Mask</td>
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<td>A7032</td>
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<td>Replacement Pillows for Nasal Application Device</td>
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<tr>
<td>A7034</td>
<td>Nasal Interface (mask or cannula type), used with positive airway pressure device, with/without head strap</td>
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<td>A7035</td>
<td>Headgear</td>
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<td>Filter, non-disposable</td>
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<tr>
<td>A7046</td>
<td>Water chamber for humidifier, replacement, each</td>
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Scope of the Guideline

This guideline is applicable to use of auto-titrating (APAP) or continuous (CPAP) positive airway pressure systems and associated supplies in the management of obstructive sleep apnea (OSA). A separate document addresses the use of bi-level positive airway pressure (BPAP). Positive airway pressure treatment modalities and add-on devices, reported using CPT code E1399 (including but not limited to the following products: Winx, PapNap, Provent, headstraps, certain dental devices, Weaver’s masks cloths) not addressed in this guideline are considered to be not medically necessary.

Overview

Positive airway pressure (PAP), resulting in pneumatic splinting of the airway, is the mainstay of treatment of OSA. The pressure provided throughout the respiratory cycle may be constant (CPAP) or may vary between inspiration and expiration (bi-level PAP or BPAP). Auto-titrating positive airway pressure (APAP) supplies variable pressure in response to changes in various parameters e.g., sleeping position, sleep stages or changes in body habitus. Although APAP may be preferred by some patients, use of APAP has not increased compliance with therapy.

For patients requiring treatment with CPAP, pressure levels need to be titrated to each patient’s particular needs. For patients whose diagnostic sleep study is performed in a lab setting, it may be possible to diagnose OSA and perform the titration study in a single night. This approach, known as split-night study, may be used when the apnea/hypopnea index (AHI) exceeds 20 per hour based on the first 2 hours of testing. Those who do not meet criteria for split-night protocol require either a second overnight titration study or temporary use of APAP as a means of titrating CPAP. Titration is not required if APAP is selected as the long-term therapeutic approach. Other treatments for OSA (not addressed in this guideline) include positional therapy, nonsurgical weight loss methods, oral appliances, oropharyngeal surgery or bariatric surgery. Tracheostomy should be considered when other measures fail and OSA is deemed severe enough to warrant this procedure. Adenotonsillectomy is the...
preferred initial approach to treatment of OSA in children. CPAP is reserved for those children who have an inadequate response to surgery, do not have enlarged tonsils or are not good surgical candidates.
In the management of patients with OSA, long-term compliance with positive airway pressure devices remains problematic. Adherence to therapy is defined by the Centers for Medicare & Medicaid Services (CMS) as use of PAP greater than or equal to 4 hours per night on 70% of nights during a consecutive thirty (30) day period. Compliance may be as low as 50% at one year and for this reason compliance monitoring is an important component of the management of patients with OSA. Every effort should be made to achieve compliance. Newer PAP devices record (and may transmit) use times such that compliance monitoring may be performed remotely. Unless compliance is achieved and documented, the continued use of PAP devices (and the ongoing provision of associated supplies) cannot be considered to be medically necessary.

**Indications for Auto-titrating Positive Airway Pressure (APAP) or Continuous Positive Airway Pressure (CPAP)**

**Treatment with CPAP is appropriate for a patient aged 19 years or older when conditions A and B below are met:**

A. Home or lab based sleep study demonstrates one of the following (1–2)
   1. AHI greater than or equal to 15
   2. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications), ischemic heart disease, history of stroke.

   **AND**

B. Appropriate CPAP level has been determined from one of the following (1–5)
   1. Split-night sleep study
   2. Whole-night lab based titration study following a study where the CPAP level was not determined during the therapeutic portion or the patient has OSA but did not meet criteria for PAP titration during the study
   3. Whole-night lab based titration study in a patient in whom APAP is contraindicated (e.g., congestive heart failure [CHF], chronic obstructive pulmonary disease [COPD])
   4. **APAP titration trial**
   5. Whole-night lab based titration study when home, unmonitored APAP titration was unsuccessful

**Treatment with CPAP is appropriate for a patient aged 18 years or younger when conditions A and B below are met**

A. A lab-based sleep study demonstrating AHI of at least one (1) and appropriate CPAP titration has been performed

   **AND**

B. One of the following (1–4) is true
   1. Adenotonsillectomy has been unsuccessful in curing OSA
   2. Adenotonsillectomy is not indicated because the patient has minimal adenotonsillar tissue
   3. Adenotonsillectomy is inappropriate because OSA is attributable to another underlying cause (e.g., craniofacial abnormality, morbid obesity)
   4. Adenotonsillectomy is contraindicated

**Treatment with APAP is appropriate when a patient meets conditions A and B below**

A. Home or lab based sleep study demonstrates one of the following (1–2)
   1. AHI greater than or equal to 15
   2. AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications), ischemic heart disease, history of stroke.

   **AND**

B. The patient has none of the following contraindications (1–5) to the use of APAP
   1. Age 18 years or younger
   2. CHF
   3. COPD
4. Central sleep apnea
5. Neuromuscular disorders (e.g. muscular dystrophy, myasthenia gravis)

**Ongoing treatment with APAP or CPAP (adult and non-adult patients)**

Ongoing treatment is indicated for patients who demonstrate compliance with therapy. Demonstration of compliance is required every (30) day period within the preceding 90 days; OR

There is clinical evidence submitted by the treating provider that demonstrates continued clinical benefit from use of the positive airway pressure device.

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**Bibliography**

**Specialty Society Guidelines and Systematic Reviews**


Other Literature


Bi-Level Positive Airway Pressure (BPAP) Devices

CPT and HCPCS Codes

E0470 ................. Respiratory assist device, bi-level pressure capability, without back-up rate feature, used with non-invasive interface (nasal or facial mask)
E0471 ................. Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with non-invasive interface (nasal or facial mask)
E0561 ................. Humidifier, non-heated, used with positive airway pressure device
E0562 ................. Humidifier, heated, used with positive airway pressure device
E1399 ................. Durable medical equipment, miscellaneous
A4604 ................. Tubing with heating element
A7027 ................. Combination Oral/Nasal Mask used with positive airway pressure device, each
A7028 ................. Oral Cushion, Replacement for Combination Oral/Nasal Mask, each
A7029 ................. Nasal Pillows, Replacement for Combination Oral/Nasal Mask, pair
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A7037 ................. Tubing
A7038 ................. Filter, disposable
A7039 ................. Filter, non-disposable
A7044 ................. Oral Interface for Positive Airway Pressure Therapy
A7045 ................. Replacement Exhalation Port for PAP Therapy
A7046 ................. Water chamber for humidifier, replacement, each

Scope of the Guideline

This guideline is applicable to patients with established sleep disorders (obstructive sleep apnea [OSA], central sleep apnea [CSA], or mixed sleep disorder), Complex Sleep Apnea, severe chronic obstructive pulmonary disease (COPD), hypoventilation syndromes and certain restrictive thoracic disorders requiring initial or ongoing therapy with bi-level positive airway pressure systems and associated supplies. Positive airway pressure treatment modalities and add-on devices, reported using CPT code E1399 (including but not limited to the following products: Winx, PapNap, Provent, headstraps, certain dental devices, Weaver’s masks cloths ) not addressed in this guideline are considered to be not medically necessary.

Overview

Bi-level positive airway pressure (BPAP) refers to a ventilation modality whereby different levels of positive airway pressure are applied during inspiration and expiration. BPAP may be administered via a non-invasive interface (whole face mask, nasal mask or nasal cushions) or via an invasive interface (endotracheal intubation or tracheostomy). This guideline is limited to the use of BPAP via non-invasive interface. Furthermore, the guideline refers to the chronic use of BPAP in the outpatient setting rather than acute inpatient use. In addition to providing positive airway pressure which varies from inspiration to expiration, some BPAP machines also have a back-up rate feature. The back-up rate feature ensures that the patient receives a minimum number of breaths per minute. Some patients who are candidates for BPAP may also benefit from the back-up rate feature (see specific indications below).

For patients requiring treatment with BPAP, pressure levels need to be titrated to each patient’s particular needs. For patients whose diagnostic sleep study is performed in a lab setting, it may be possible to diagnose OSA and perform the titration study in a single night. This approach, known as split-night study, may be used when the apnea/hypopnea index (AHI) exceeds 20 per hour based on the first 2 hours of testing. Those who do not meet criteria for split-night protocol require either a second overnight titration study or temporary use of auto-titrating BPAP without a back-up rate as a means of BPAP titration for those....
patients who do not require a back-up rate. Titration may not be required if auto-tri-trating BPAP is selected as the long-term therapeutic approach.

As with other positive airway pressure (PAP) therapies, long term compliance is an issue. Adherence to therapy is defined by the Centers for Medicare & Medicaid Services (CMS) as use of PAP greater than or equal to 4 hours per night on 70% of nights during a consecutive thirty (30) day period. Compliance may be as low as 50% at one year and for this reason compliance monitoring is an important coponent of the management of patients using BPAP. Every effort should be made to achieve compliance. Newer PAP devices record (and may transmit) use times such that compliance monitoring may be performed remotely. Unless compliance is achieved and documented, the continued use of PAP devices (and the ongoing provision of associated supplies) cannot be considered to be medically necessary.

Indications for Bi-Level Positive Airway Pressure Devices (BPAP)

BPAP (without back-up rate feature)
- Appropriate for patients with OSA who have failed CPAP/APAP or require supplemental ventilatory support due to a hypoventilation syndrome.

BPAP (with back-up rate feature)
- Appropriate for patients with established CSA diagnosed by an in-lab sleep study demonstrating all of the following (a-c):
  a. OSA has been excluded or treated. Patients with CSA may also have OSA.

Central sleep apnea (CSA) is defined by all of the following:

1. An apnea-hypopnea index (AHI) greater than or equal to 5; and,
2. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and,
3. A central apnea-central hypopnea index (CAHI) is greater than or equal to 5 per hour; and,
4. The presence of at least one of the following:
   - Sleepiness
   - Difficulty initiating or maintaining sleep, frequent awakenings, or non-restorative sleep
   - Awakening short of breath
   - Snoring
   - Witnessed apneas

5. There is no evidence of daytime or nocturnal hypoventilation. For diagnosis of CSA, the central apnea-central hypopnea index (CAHI) is defined as the average number of episodes of central apnea and central hypopnea per hour of sleep without the use of a positive airway pressure device.

Complex sleep apnea (CompSA) The following is Medicare’s RAD LCD definition:

Complex sleep apnea (CompSA) is a form of central apnea specifically identified by all the following:

1. With use of a positive airway pressure device without a backup rate (E0601 or E0470), the polysomnogram (PSG) shows a pattern of apneas and hypopneas that demonstrates the persistence or emergence of central apneas or central hypopneas upon exposure to CPAP (E0601) or a bi-level device without backup rate (E0470) device when titrated to the point where obstructive events have been effectively treated (obstructive AHI less than 5 per hour).
2. After resolution of the obstructive events, the sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
3. After resolution of the obstructive events, a central apnea-central hypopnea index (CAHI) greater than or equal to 5 per hour. For CompSA, the CAHI (central apnea-central hypopnea index) is determined during the use of a positive airway pressure device after obstructive events have disappeared.

BPAP (with or without back-up rate feature)
- Appropriate in the management of patients with severe COPD demonstrating either of the following (a or b):
  a. PaCO2 measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FIO2 is 45 mmHg or greater; OR
  b. Sleep oximetry demonstrates oxygen saturation of 88% or less for at least five continuous minutes while the patient breathes oxygen at 21% per minute or his/her usual FIO2 (whichever is higher).

BPAP (with or without back-up rate feature)
- Appropriate in the management of patients with certain restrictive thoracic disorders when both a and b below are true
  a. The patient has an established diagnosis of a progressive neuromuscular disease, e.g., amyotrophic lateral sclerosis (ALS) OR a severe thoracic cage abnormality; AND
  b. One of the following statements is true:
     ■ PaCO2 measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FIO2 is 45 mmHg or greater.
     ■ Sleep oximetry demonstrates oxygen saturation of 88% or less for at least five continuous minutes while the patient breathes his/her usual FIO2.
     ■ For a neuromuscular disease (only), either 1 or 2
       1. Maximal inspiratory pressure is less than 60 cm H2O.
       2. Forced vital capacity is less than 50% of predicted

Hypoventilation Syndrome
BPAP (with back-up rate feature)
- Appropriate in the management of patient with Hypoventilation Syndrome
  o. An initial arterial blood gas PaCO2, done while awake and breathing the beneficiary's prescribed FIO2, is greater than or equal to 45 mm Hg.
  o. Spirometry shows an FEV1/FVC greater than or equal to 70%. (Refer to SEVERE COPD (above) for information about device coverage for beneficiaries with FEV1/FVC less than 70%).
  o. A facility-based PSG or HST demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI less than 5.

Ongoing treatment with BPAP:
Ongoing treatment is indicated for patients who demonstrate compliance with therapy. Demonstration of compliance is required every during the first 90 days of treatment. Request by the beneficiary for the replacement of PAP accessories is a clear indication of treatment compliance. For the first year of treatment and annually thereafter, Compliance is defined as:

1. Use of the BPAP device for greater than or equal to four (4) hours per night on 70% of nights during a consecutive thirty (30) day period within the preceding 90 days; OR
2. There is clinical evidence submitted by the treating provider that demonstrates continued clinical benefit from use of the positive airway pressure device.

**Bibliography**

**Specialty Society Guidelines and Systematic Reviews**


**Other Literature**

Management of Obstructive Sleep Apnea (OSA) using Oral Appliances

CPT and HCPCS Codes

E0485 ................. Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment

E0486 ................. Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

Scope of the Guideline

This guideline is applicable to use of oral appliances in the management of obstructive sleep apnea (OSA). The term oral appliance (OA) includes mandibular repositioning appliances (MRA) and tongue retaining devices (TRD). This document refers to both custom-made devices (CPT code E0486) and over-the-counter or prefabricated devices (CPT code E0485).

Overview

In addition to lifestyle changes, (weight loss, avoidance of alcohol and sedatives etc.) positive airway pressure (PAP) therapy is considered to be the first-line approach to the management of patients with all degrees of obstructive sleep apnea. For patients who have mild or moderate OSA, certain OAs may be used as an alternative to PAP therapy in patients who are intolerant of PAP therapy, those for whom PAP therapy is ineffective, and those who prefer to consider an OA rather than PAP as a first line therapy. It is highly recommended that the decision to use an OA in the management of OSA should follow consultation with a sleep medicine specialist. Mandibular repositioning appliances (MRA) cover the upper and lower teeth and hold the mandible in an advanced position with respect to the resting position. Tongue retaining devices (TRD) hold only the tongue in a forward position with respect to the resting position, without mandibular repositioning. Both appliances change the contour of the upper airway such that the likelihood of airway collapse during sleep is reduced. When MRAs are used in the management of OSA, they must comply with all of the following specifications as outlined by Centers for Medicare and Medicaid Services (CMS):

- Have a fixed mechanical hinge at the sides, front, or palate
- Have a mechanism that allows the mandible to be advanced in increments of one millimeter or less
- Be able to protrude the mandible beyond the front teeth at maximum protrusion
- Be adjustable by the beneficiary in increments of one millimeter or less
- Retain the adjustment setting when removed
- Maintain mouth position during sleep so as to prevent dislodging the device.

Indications for Custom Fabricated Oral Appliances (CPT E0486)

Treatment with OA is appropriate for patients with severe OSA (apnea/hypopnea index [AHI] greater than 30) meeting both of the following criteria (A-B) below:

A. The appliance is a TRD or a MRA which complies with CMS criteria AND

B. One of the following (a-c) applies
   a. The patient is not a candidate for positive airway pressure therapy; or
   b. Positive airway pressure therapy has not been effective despite a 45 day trial and participation in a positive airway pressure compliance program; or
   c. The patient has tried continuous positive airway pressure (CPAP) but has not been compliant despite a 45 day trial and participation in a positive airway pressure compliance program.

Treatment with OA is appropriate for patients with mild or moderate OSA meeting all of the following criteria (A-C) below:

- CMS' E0486 criteria is too restrictive as it limits E0486 devices to outdated “Herbst-like” devices that have a “fixed-mechanical hinge.”
- Per Medicare’s Coverage Article A52512, the HCPCS E0486 definition requires that custom MRDs must meet additional specific criteria. One problematic and anticipated criteria is “a fixed mechanical hinge at the sides, front or palate”:
  - A fixed hinge is defined as a mechanical joint, containing an inseparable pivot point. Interlocking flanges, tongue and groove mechanisms, hook and loop or hook and eye clasps, elastic straps or bands, etc. (not all-inclusive) do not meet this requirement.
- A fixed mechanical hinge is not applicable for effective and safe OA therapy.
- The Narval MRDs do not have fixed mechanical hinges and are effective for mild to severe OSA in patients who refuse or are noncompliant with CPAP. They are well tolerated and have excellent compliance. Vecchierini M. et al. A custom-made mandibular repositioning device for obstructive sleep apnoea-hypopnoea syndrome: the ORCADES study. Sleep Medicine 2015

Clinical Choice Matters:

AIM and Medicare need to adopt a policy that does not restrict beneficiary access to non-fixed hinge devices like MicroO2, Narval, and SomnoMed. Having a range of devices to choose from is an important part of a physician appropriate appliance selection. Schwartz, D. Eeny Meeny Miny Moe: Selecting an Appropriate Appliance for Your Patients. Dental Sleep Practice. Summer, 2015, pp. 38-41.
Prefabricated Oral Appliances (CPT E0485)

Prefabricated oral appliances are not considered to be appropriate therapy for obstructive sleep apnea in any clinical situation.

Bibliography

Specialty Society Guidelines and Systematic Reviews


Other Literature


Commented [CJS15]: CMS’ E0486 criteria is too restrictive as it limits E0486 devices to outdated “Herbst-like” devices that have a “fixed-mechanical hinge.”

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  • A fixed mechanical hinge is not applicable for effective and safe OA therapy.


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### Relevant Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AHI</td>
<td>Apnea/hypopnea index</td>
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<td>Automatically titrating positive airway pressure</td>
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<td>Body mass index</td>
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<td>Bi-level positive airway pressure</td>
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<td>Chronic obstructive pulmonary disease</td>
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<td>FEV1</td>
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