









## 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 symptoms including morning headache, poor concentration, memory impairment, irritability, decreased libido, and nocturia. 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.

**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. Regardless of the location at which the service is performed, diagnostic sleep tests should be reported by a physician.

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### 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. 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 apneic, hypopneic 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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### 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

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

**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 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) and devices which utilize the combination of peripheral arterial tone (PAT), actigraphy, EKG/heart rate and oxygen saturation are considered medically necessary when the criteria below are met. Type IV devices not meeting this description 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/m<sup>2</sup> 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 bradycardic arrhythmias in patients who meet one of the criteria in 2a–e above.

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### 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.
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**Table 1: Contraindications to Home Sleep Study**

1. Patient is 18 years old or younger
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
3. Moderate or severe congestive heart failure (CHF) – New York Heart Association (NYHA) class III or IV
4. CHF with a history of ventricular fibrillation or sustained ventricular tachycardia in a patient who does not have an implanted defibrillator
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
6. Physical impairment resulting in inability to apply the home sleep testing equipment when another individual is not available to assist with this task
7. The patient has a suspected or established diagnosis of one of the following conditions: (a) Central Sleep Apnea, (b) Periodic Limb Movement Disorder (PLMD), (c) Narcolepsy, (d) Idiopathic Hypersomnia, (e) Parasomnia (except bruxism and somniloqui [sleep talking]), (f) Nocturnal Seizures – In order to support the suspicion of PLMD in this context, <u>one</u> of the following (i-vi) must be documented: (i) Pregnancy, (ii) Renal failure, (iii) Iron deficiency anemia, (iv) Peripheral neuropathy, (v) Use of antidepressant or antipsychotic medications, or (vi) Continued hypersomnia and clinical symptoms of PLMD after sleep disordered breathing is ruled out by home sleep testing.
8. Previous technically suboptimal home sleep study (2 nights of study attempted when the reason for the suboptimal study is likely to recur on a second attempt or when the study remains suboptimal after 2 nights have been attempted)
9. Previous 2-night home sleep study which did not diagnose OSA in a patient with ongoing clinical suspicion of OSA.
10. Patient is oxygen dependent for any reason
11. History of cerebrovascular accident (CVA) within the preceding 30 days
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.
13. Body Mass Index (BMI) >33 and elevated serum bicarbonate level (>28 mmol/L)
14. Established diagnosis of obesity hypoventilation syndrome defined as a body mass index (BMI) >30 kg/m <sup>2</sup> and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology or medications. Documentation of hypoventilation requires either an increase in arterial PCO <sub>2</sub> (or surrogate measure) to >55 mmHg for at least 10 minutes <u>or</u> a >10 mmHg increase in arterial PCO <sub>2</sub> (or surrogate measure) during sleep (compared to an awake supine value) to a value exceeding 50 mmHg for at least 10 minutes.

# 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 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/m<sup>2</sup> 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.

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## **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. Parasomnia
5. Idiopathic hypersomnia
6. Periodic limb movement disorder (PLMD) – In order to support the suspicion of PLMD in this context, one of the following (i–vi) must be documented: (i) Pregnancy, (ii) Renal failure, (iii) Iron deficiency anemia, (iv) Peripheral neuropathy, (v) use of antidepressant or antipsychotic medications, or (vi) continued hypersomnia and clinical symptoms of PLMD after sleep disordered breathing is ruled out by home sleep testing.
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

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## **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.

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### 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.

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# 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.

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### **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.

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### **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.

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### **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)

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### 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

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### 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)

## References

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



## CPT and HCPCS Codes

E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Single level continuous positive airway pressure device or auto-titrating continuous positive airway pressure
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
A7030	Full Face Mask used with positive airway pressure device, each
A7031	Face Mask Cushion, Replacement for Full Face Mask
A7032	Replacement Cushion for Nasal Application Device
A7033	Replacement Pillows for Nasal Application Device, pair
A7034	Nasal Interface (mask or cannula type), used with positive airway pressure device, with/without head strap
A7035	Headgear
A7036	Chinstrap
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 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: 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, non-surgical 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], obesity hypoventilation syndrome or central sleep apnea [defined as having at least 50% central events or more than five (5) central events per hour])
  - 4. APAP titration trial
  - 5. Whole-night lab based titration study when home, unmonitored APAP titration was unsuccessful

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**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

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**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 (1–6) to the use of APAP
  - 1. Age 18 years or younger
  - 2. CHF
  - 3. COPD
  - 4. Central sleep apnea (defined as having at least 50% central events or more than five [5] central events per hour)
  - 5. Neuromuscular disorders (e.g. muscular dystrophy, myasthenia gravis)



6. Obesity hypoventilation syndrome defined as a body mass index (BMI) >30 kg/m<sup>2</sup> and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology or medications. Documentation of hypoventilation requires either an increase in arterial PCO<sub>2</sub> (or surrogate measure) to >55 mmHg for at least 10 minutes or a >10 mmHg increase in arterial PCO<sub>2</sub> (or surrogate measure) during sleep (compared to an awake supine value) to a value EXCEEDING 50 mmHg for at least 10 minutes.

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### 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 90 days for the first year of therapy and annually thereafter. Compliance is defined as:

1. Use of the CPAP 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.

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# 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
A7030	Full Face Mask used with positive airway pressure device, each
A7031	Face Mask Cushion, Replacement for Full Face Mask
A7032	Replacement Cushion for Nasal Application Device
A7033	Replacement Pillows for Nasal Application Device, pair
A7034	Nasal Interface (mask or cannula type), used with positive airway pressure device, with/without head strap
A7035	Headgear
A7036	Chinstrap
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 disorders), severe chronic obstructive pulmonary disease (COPD) 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: 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 as a means of BPAP titration. Titration may not be required if auto-titrating 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 component 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
- Appropriate for patients with established CSA diagnosed by an in-lab sleep study when both of the following (a and b) apply:
  - a. OSA has been excluded or treated
  - b. A titration study (split-night or whole-night) has demonstrated significant improvement of sleep-related hypoventilation adjusted to the settings that will be prescribed for home use (while breathing the individual's usual FiO<sub>2</sub>)

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### BPAP (with back-up rate feature)

- Appropriate for patients with established CSA diagnosed by an in-lab sleep study and all of the following (a–c) apply:
  - a. OSA has been excluded or treated
  - b. BPAP without back-up rate had been attempted but has not successfully treated episodes of desaturation as evidenced by either of the following:
    - Oxygen saturation level is 88% or less for at least five (5) minutes while the patient breathes his/her usual FiO<sub>2</sub>;
    - OR**
    - The patient demonstrates Cheyne Stokes respiration for five (5) continuous minutes with oxygen saturation falling to less than 88% at least once during that 5-minute interval
  - c. A titration study (split-night or whole-night) has demonstrated significant improvement of sleep-related hypoventilation adjusted to the settings that will be prescribed for home use (while breathing the individual's usual FiO<sub>2</sub>)

*Note: Use of BPAP in Adaptive Servo-Ventilation (ASV) mode for management of patients with CSA is appropriate only when left ventricular ejection fraction (LVEF) is >45%.*

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### 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. PaCO<sub>2</sub> measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO<sub>2</sub> 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 2L per minute or his/her usual FiO<sub>2</sub> (whichever is higher)

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## 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:
    - PaCO<sub>2</sub> measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO<sub>2</sub> 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 FiO<sub>2</sub>
    - Maximal inspiratory pressure is less than 60 cm H<sub>2</sub>O or forced vital capacity is less than 50% of predicted (applies to patients with progressive neuromuscular disease only)

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## Ongoing treatment with BPAP:

Ongoing treatment is indicated for patients who demonstrate compliance with therapy. Demonstration of compliance is required every 90 days 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.

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# 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. Custom made oral appliances require a prescription from a medical provider.

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.

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

- A. At least one of the following:
  - a. AHI greater than or equal to 15 and less than or equal to 30; **or**
  - b. 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. At least one of the following:
  - 1. The patient is not a candidate for positive airway pressure therapy; **or**
  - 2. Positive airway pressure therapy has not been effective despite a 45 day trial and participation in a positive airway pressure compliance program; **or**
  - 3. The patient has tried CPAP but has not been compliant despite a 45 day trial and participation in a positive airway pressure compliance program; **or**
  - 4. The patient prefers to use an OA rather than PAP as the initial therapy; **AND**
- C. The appliance is a TRD or a MRA which complies with CMS criteria

## Prefabricated Oral Appliances (CPT E0485)

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

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## Relevant Abbreviations and Acronyms

AHI	Apnea/hypopnea index
ALS	Amyotrophic lateral sclerosis
APAP	Automatically titrating positive airway pressure
BMI	Body mass index
BPAP	Bi-level positive airway pressure
CHF	Congestive heart failure
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
CSA	Central sleep apnea
EEG	Electroencephalogram
EKG	Electrocardiogram
EMG	Electromyogram
EOG	Electrooculogram
FEV1	Forced expiratory volume in 1 second
FiO <sub>2</sub>	Fraction of inspired oxygen
FVC	Forced vital capacity
MRA	Mandibular repositioning appliance
NYHA	New York Heart Association
OA	Oral appliance
OSA	Obstructive sleep apnea
PaCO <sub>2</sub>	Partial pressure of carbon dioxide in arterial blood
PAP	Positive airway pressure
PLMD	Periodic limb movement disorder
PSG	Polysomnography
RDI	Respiratory disturbance index
REM	Rapid eye movement
RERA	Respiratory effort related arousal
TRD	Tongue retaining device