

Sleep Disorder Management Diagnostic & Treatment Guidelines

Clinical Appropriateness Guidelines

Effective Date: March 9, 2019

Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details. AIM Specialty Health disclaims any responsibility for the completeness or accuracy of the information contained herein.

Proprietary

ARCHIVED JUNE 29, 2019

These documents have been archived because they have outdated information. They are for historical information only and should not be consulted for clinical use. Current versions of guidelines are available on the AIM Specialty Health website at <http://www.aimspecialtyhealth.com/>

Date of Origin: 05/04/2012
Last revised: 04/12/2018
Last reviewed: 04/12/2018



Clinical & Regulatory Guidelines
8600 W Bryn Mawr Avenue
South Tower - Suite 800
Chicago, IL 60631
P. 773.864.4600
www.aimspecialtyhealth.com

Table of Contents



Description and Application of the Guidelines.....	3
General Clinical Guideline.....	4
Sleep Disorder Diagnostic Management Guidelines	6
<i>Polysomnography and Home Sleep Testing.....</i>	<i>6</i>
<i>Multiple Sleep Latency Testing and Maintenance of Wakefulness Testing</i>	<i>13</i>
Sleep Disorder Treatment Management Guidelines.....	15
<i>Management of Obstructive Sleep Apnea using APAP and CPAP Devices</i>	<i>15</i>
<i>Bi-Level Positive Airway Pressure (BPAP) Devices</i>	<i>19</i>
<i>Management of Obstructive Sleep Apnea using Oral Appliances.....</i>	<i>22</i>
Glossary	25

ARCHIVED

Description and Application of the Guidelines



AIM's Clinical Appropriateness Guidelines (hereinafter "AIM's Clinical Appropriateness Guidelines" or the "Guidelines") are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by AIM, the Guidelines establish objective and evidence-based, where possible, criteria for medical necessity determinations. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of healthcare
- To promote the most efficient and cost-effective use of services

AIM's guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up to date clinical principles and best practices. Relevant citations are included in the "References" section attached to each Guideline. AIM reviews all of its Guidelines at least annually.

AIM makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of AIM's Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, AIM considers the Guidelines to be important, proprietary information of AIM, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of AIM.

AIM applies objective and evidence-based criteria and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The AIM Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines. If requested by a health plan, AIM will review requests based on health plan medical policy/guidelines in lieu of AIM's Guidelines.

The Guidelines may also be used by the health plan or by AIM for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature and other data are copyright by the American Medical Association. All Rights Reserved. AMA does not directly or indirectly practice medicine or dispense medical services. AMA assumes no liability for the data contained herein or not contained herein.

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered.

History

Status	Date	Action
Revised	03/09/2019	Retitled Pretest Requirements to “Clinical Appropriateness Framework” to summarize the components of a decision to pursue diagnostic testing. To expand applicability beyond diagnostic imaging, retitled Ordering of Multiple Studies to “Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions” and replaced imaging-specific terms with “diagnostic or therapeutic intervention.” Repeated Imaging split into two subsections, “repeat diagnostic intervention” and “repeat therapeutic intervention.”
Reviewed	07/11/2018	Last Independent Multispecialty Physician Panel review
Revised	07/26/2016	Independent Multispecialty Physician Panel revised
Created	03/30/2005	Original effective date

ARCHIVED

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:
 - Confusion arousals
 - Somnambulism (sleepwalking)
 - Sleep terrors
 - Rapid eye movement (REM) sleep behavior disorder
 - Sleep-related epilepsy
 - Sleep bruxism
 - Sleep enuresis (bed wetting)
 - 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 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.

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.

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/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 bradycardic 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

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 ² and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology or medications. Documentation of hypoventilation requires either an increase in arterial PCO ₂ (or surrogate measure) to >55 mmHg for at least 10 minutes <u>or</u> a >10 mmHg increase in arterial PCO ₂ (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/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. 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

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.

References

Specialty Society Guidelines and Systematic Reviews

1. Aurora RN, Casey KR, Kristo D, et al.; American Academy of Sleep Medicine. Practice parameters for the surgical modifications of the upper airway for obstructive sleep apnea in adults. *Sleep*. 2010;33(10):1408-1413.
2. Aurora RN, Zak RS, Karipott A, et al.; American Academy of Sleep Medicine (AASM). Practice parameters for the respiratory indications for polysomnography in children. *Sleep*. 2011; 34(3):379-388.
3. Balk EM, Moorthy D, Obadan NO, et al. *Diagnosis and Treatment of Obstructive Sleep Apnea in Adults*. Comparative Effectiveness Review No. 32. Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-10055-1. AHRQ Publication No. 11-EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality; July 2011.
4. Canadian Agency for Drugs and Technologies in Health (CADTH). *Portable Monitoring Devices for Diagnosis of Obstructive Sleep Apnea at Home: Review of Accuracy, Cost-Effectiveness, Guidelines, and Coverage in Canada*. December 2009.
5. Epstein LJ, Kristo D, Strollo PJ, et al.; American Academy of Sleep Medicine. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009;5(3):263-276.
6. Gleitsmann K, Kriz H, Thielka A, et al. *Sleep Apnea Diagnosis and Treatment in Adults*. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University; 2012.
7. Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017;13(3):479–504.
8. Marcus CL, Brooks LJ, Draper KA, et al.; American Academy of Pediatrics. Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome. *Pediatrics*. 2012;130(3):576-584.
9. Roland PS, Rosenfeld RM, Brooks LJ, et al; American Academy of Otolaryngology—Head and Neck Surgery Foundation. Clinical practice guideline: polysomnography for sleep-disordered breathing prior to tonsillectomy in children. *Otolaryngol Head Neck Surg*. 2011 Jul;145(1 Suppl):S1-15.

Other Literature

1. Berry RB, Hill G, Thompson L, McLaurin V. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. *Sleep*. 2008;31(10):1423-1431.
2. Collop NA, Anderson WM, Boehlecke B, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med*. 2007;3(7):737-747.
3. de Oliveira ACT, Martinez D, Vasconcelos LFT, et al. Diagnosis of obstructive sleep apnea syndrome and its outcomes with home portable monitoring. *Chest*. 2009;135(2):330-336.
4. El Shayeb M, Topfer LA, Stafinski T, Pawluk L, Menon D. Diagnostic accuracy of level 3 portable sleep tests versus level 1 polysomnography for sleep-disordered breathing: a systematic review and meta-analysis. *CMAJ*. 2014;186(1):E25-E51.
5. Kuna ST, Gurubhagavatula I, Maislin G, et al. Noninferiority of functional outcome in ambulatory management of obstructive sleep apnea. *Am J Respir Crit Care Med*. 2011;183(9):1238-1244.
6. Levendowski D, Steward D, Woodson BT, et al. The impact of obstructive sleep apnea variability measured in-lab versus in-home on sample size calculations. *Int Arch Med*. 2009;2(1):2.
7. Mulgrew AT, Fox N, Ayas NT, Ryan CF. Diagnosis and initial management of obstructive sleep apnea without polysomnography a randomized validation study. *Ann Intern Med*. 2007;146:157-166.
8. Rosen CL, Auckley D, Benca R, et al. A multisite randomized trial of portable sleep studies and positive airway pressure autotitration versus laboratory-based polysomnography for the diagnosis and treatment of obstructive sleep apnea: the Home PAP Study. *Sleep*. 2012;35(6):757-767.
9. Skomro RP, Gjevre J, Reid J, et al. Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. *Chest*. 2010;138(2): 257-263.
10. Townsend D, Sharma A, Brauer E, et al. Assessing efficacy, outcomes, and cost savings for patients with obstructive sleep apnea using two diagnostic and treatment strategies. *Sleep Diagnosis Therapy*. 2007;1(7):1-8.

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)

References

Specialty Society Guidelines and Systematic Reviews

1. Aurora RN, Lamm CI, Zak RS, et al; American Academy of Sleep Medicine. Practice parameters for the non-respiratory indications for polysomnography and multiple sleep latency testing for children. *Sleep* 2012;35(11):1467-1473.
2. Littner MR, Kushida C, Wise M, et al; American Academy of Sleep Medicine. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. *Sleep*. Jan 1 2005;28(1):113-121.
3. Morgenthaler TI, Kapur VK, Brown T, et al; American Academy of Sleep Medicine. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. *Sleep*. 2007;30(12):1705-1711.

Other Literature

1. American Academy of Sleep Medicine. *International Classification of Sleep Disorders*, 3rd ed. Darien, IL: AASM; 2014.
2. Zeman A, Britton T, Douglas N, et al. Narcolepsy and excessive daytime sleepiness. *BMJ*. 2004; 329:724-728.

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

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 (1–6) 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/m² 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 PCO₂ (or surrogate measure) to >55 mmHg for at least 10 minutes or a >10 mmHg increase in arterial PCO₂ (or surrogate measure) during sleep (compared to an awake supine value) to a value EXCEEDING 50 mmHg for at least 10 minutes.

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.

References

Specialty Society Guidelines and Systematic Reviews

1. Aurora RN, Chowdhuri S, Ramar K, et al. The treatment of central sleep apnea syndromes in adults: practice parameters with an evidence-based literature review and meta-analyses. *Sleep*. 2012;35(1):17-40.
2. Ayas NT, Patel SR, Malhostra A, et al. Auto-titrating vs. standard continuous positive airway pressure for the treatment of obstructive sleep apnea: results of a meta-analysis. *Sleep*. 2004;27(2):249-253.
3. Balk EM, Moorthy D, Obadan NO, et al. *Diagnosis and Treatment of Obstructive Sleep Apnea in Adults*. Comparative Effectiveness Review No. 32. Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-10055-1. AHRQ Publication No. 11-EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality; July 2011.
4. Canadian Agency for Drugs and Technologies in Health (CADTH). *Portable Monitoring Devices for Diagnosis of Obstructive Sleep Apnea at Home: Review of Accuracy, Cost-Effectiveness, Guidelines, and Coverage in Canada*. December 2009.
5. Centers for Medicare and Medicaid Services. *National Coverage Determination for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (240.4)*. Effective March 13, 2008. Available at <http://www.cms.gov/medicare-coverage-database/>. Accessibility verified September 27, 2017.
6. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009;5(3):263-276.
7. Gay P, Weaver T, Loube D, et al; American Academy of Sleep Medicine. Evaluation of positive airway pressure treatment for sleep-related breathing disorders in adults. *Sleep*. 2006;29(3):381-401.
8. Gleitsmann K, Kriz H, Thielka A, et al. *Sleep Apnea Diagnosis and Treatment in Adults*. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University; 2012.
9. Marcus CL, Brooks LJ, Draper KA, et al.; American Academy of Pediatrics. Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome. *Pediatrics*. 2012;130(3):576-584.
10. Morgenthaler TI, Aurora RN, Brown T, et al. Practice parameters for the use of autotitrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea syndrome: an update for 2007. *Sleep*. 2008;31(1):141-147.
11. Qaseem A, Holty JE, Owens DK, Dallas P, Starkey M, Shekelle P; Clinical Guidelines Committee of the American College of Physicians. Management of Obstructive Sleep Apnea in Adults: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. 2013;159:471-483.
12. Vital FM, Ladeira MT, Atallah AN. Non-invasive positive pressure ventilation (CPAP or bilevel NPPV) for cardiogenic pulmonary oedema. *Cochrane Database Syst Rev*. 2013 May 31;5:CD005351.
13. Xu T, Li T, Wei D, et al. Effect of automatic versus fixed continuous positive airway pressure for the treatment of obstructive sleep apnea: an up-to-date meta-analysis. *Sleep Breath*. 2012;16(4):1017-1026.

Other Literature

1. Berry RB, Hill G, Thompson L, McLaurin V. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. *Sleep*. 2008;31(10):1423-1431.
2. Boyacı H, Gacar K, Barış SA, Başığit I, Yıldız F. Positive airway pressure device compliance of the patients with obstructive sleep apnea syndrome. *Adv Clin Exp Med*. 2013;22(6):809-815.
3. Heiser C, Maurer JT, Hofauer B, Sommer JU, Seitz A, Steffen A. Outcomes of Upper Airway Stimulation for Obstructive Sleep Apnea in a Multicenter German Postmarket Study. *Otolaryngol Head Neck Surg*. 2017;156(2):378-384.
4. Hertegonne K, Bauters F. The value of auto adjustable CPAP devices in pressure titration and treatment of patients with obstructive sleep apnea syndrome. *Sleep Med Rev*. 2010;14:115-119.
5. Kuna ST. Noninferiority of functional outcome in ambulatory management of obstructive sleep apnea. *Am J Respir Crit Care Med* 2011; 183(9): 1238-1244.
6. Marcus CL, Beck SE, Traylor J, et al. Randomized, double-blind clinical trial of two different modes of positive airway pressure therapy on adherence and efficacy in children. *J Clin Sleep Med*. 2012 Feb 15;8(1):37-42.
7. Massie CA, McArdle N, Hart RW, et al. Comparison between automatic and fixed positive airway pressure therapy in the home. *Am J Respir Crit Care Med*. 2003;167(1):20-23.
8. Ozsancak A, D'Ambrosio C, Hill NS. Nocturnal noninvasive ventilation. *Chest*. 2008;133(5):1275-1286.
9. Pedrosa RP, Drager LF, de Paula LK, et al. Effects of OSA treatment on BP in patients with resistant hypertension: a randomized trial. *Chest*. 2013;144(5):1487-1494.
10. Rosen CL. A multisite randomized trial of portable sleep studies and positive airway pressure autotitration versus laboratory-based polysomnography for the diagnosis and treatment of obstructive sleep apnea: the Home PAP Study. *Sleep*. 2012;35(6):757-767.
11. Schwab RJ, Badr SM, Epstein LJ, et al.; ATS Subcommittee on CPAP Adherence Tracking Systems. An official American Thoracic Society statement: continuous positive airway pressure adherence tracking systems. The optimal monitoring strategies and outcome measures in adults. *Am J Respir Crit Care Med*. 2013;188(5):613-620.
12. Skomro RP, Gjevre J, Reid J, et al. Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. *Chest*. 2010;138(2):257-263.

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 FiO₂)

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 FiO₂; **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 FiO₂)

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%.

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 2L 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
 - Maximal inspiratory pressure is less than 60 cm H₂O or forced vital capacity is less than 50% of predicted (applies to patients with progressive neuromuscular disease only)

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.

References

Specialty Society Guidelines and Systematic Reviews

1. Aurora RN, Bista SR, Casey KR, et al. Updated adaptive servo-ventilation recommendations for the 2012 AASM guideline: "The treatment of central sleep apnea syndromes in adults: Practice parameters with an evidence-based literature review and meta-analyses". *J Clin Sleep Med*. 2016;12(5):757-61.
2. Aurora RN, Chowdhuri S, Ramar K, et al. The treatment of central sleep apnea syndromes in adults: practice parameters with an evidence-based literature review and meta-analyses. *Sleep*. 2012;35(1):17-40.
3. Balk EM, Moorthy D, Obadan NO, et al. *Diagnosis and Treatment of Obstructive Sleep Apnea in Adults*. Comparative Effectiveness Review No. 32. Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-10055-1. AHRQ Publication No. 11-EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality; July 2011.
4. Cowie MR, Woehrle H, Wegscheider K, et al. Adaptive Servo-Ventilation for Central Sleep Apnea in Systolic Heart Failure. *N Engl J Med*. 2015;373(12):1095-105.
5. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009;5(3):263-276.
6. Kushida CA, Chediak A, Berry RB, et al. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. *J Clin Sleep Med*. 2008;4(2):157-171.
7. Kushida CA, Littner MR, Hirshkowitz M, et al; American Academy of Sleep Medicine. Practice parameters for the use of continuous and bilevel positive airway pressure devices to treat adult patients with sleep-related breathing disorders. *Sleep*. 2006;29(3):375-380.
8. Vital FM, Ladeira MT, Atallah AN. Non-invasive positive pressure ventilation (CPAP or bilevel NPPV) for cardiogenic pulmonary oedema. *Cochrane Database Syst Rev*. 2013 May 31;5:CD005351.

Other Literature

1. Bonekat HW. Noninvasive ventilation in neuromuscular disease. *Crit Care Clin*. 1998;14(4):775-797.
2. Hill NS. Noninvasive ventilation in chronic obstructive pulmonary disease. *Clin Chest Med*. 2000 Dec;21(4):783-797.
3. Keenan SP, Mehta S. Noninvasive ventilation for patients presenting with acute respiratory failure: the randomized controlled trials. *Respir Care*. 2009;54(1):116-26.
4. Ozsancak A, D'Ambrosio C, Hill NS. Nocturnal noninvasive ventilation. *Chest*. 2008;133(5):1275-1286.

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.

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

References

Specialty Society Guidelines and Systematic Reviews

1. Balk EM, Moorthy D, Obadan NO, et al. *Diagnosis and Treatment of Obstructive Sleep Apnea in Adults*. Comparative Effectiveness Review No. 32. Prepared by Tufts Evidence-based Practice Center under Contract No. 290-2007-10055-1. AHRQ Publication No. 11-EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality; July 2011.
2. Epstein LJ, Kristo D, Strollo PJ, et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med*. 2009;5(3):263-276.
3. Gay P, Weaver T, Loube D, et al; American Academy of Sleep Medicine. Evaluation of positive airway pressure treatment for sleep-related breathing disorders in adults. *Sleep*. 2006;29(3):381-401.
4. Kushida CA, Morgenthaler TI, Littner MR, et al. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances: an update for 2005. *Sleep*. 2006;29(2):240-243.
5. Qaseem A, Holty JE, Owens DK, Dallas P, Starkey M, Shekelle P; Clinical Guidelines Committee of the American College of Physicians. Management of Obstructive Sleep Apnea in Adults: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. 2013;159:471–483.

Other Literature

1. Doff MH, Hoekema A, Wijkstra PJ, et al. Oral appliance versus continuous positive airway pressure in obstructive sleep apnea syndrome: a 2-year follow-up. *Sleep*. 2013;36(9):1289-1296.
2. Ferguson KA, Cartwright R, Rogers R, Schmidt-Nowara W. Oral appliances for snoring and obstructive sleep apnea: a review. *Sleep*. 2006; 29(2):244-262.
3. Kastoer C, Dieltjens M, Oorts E, et al. The use of remotely controlled mandibular positioner as a predictive screening tool for mandibular advancement device therapy in patients with obstructive sleep apnea through single-night progressive titration of the mandible: a systematic review. *J Clin Sleep Med*. 2016;12(10):1411–1421.
4. Krishnan V, Collop NA, Scherr SC. An evaluation of a titration strategy for prescription of oral appliances for sleep apnea. *Chest*. 2008;133(5):1135-1141.

5. Lam B, Sam K, Mok WY, et al. Randomised study of three non-surgical treatments in mild to moderate obstructive sleep apnoea. *Thorax*. 2007;62(4):354-359.
6. Li W, Xiao L, Hu J. The comparison of CPAP and oral appliances in treatment of patients with OSA: a systematic review and meta-analysis. *Respir Care*. 2013;58(7):1184-1195.
7. *Local Coverage Article: Oral Appliances for Obstructive Sleep Apnea - Policy Article - Effective October 2015 (A52512)*. CGS Administrators, LLC; Noridian Healthcare Solutions, LLC. All 50 U.S. states and the District of Columbia, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and U.S. Virgin Islands. Available at <http://www.cms.gov/medicare-coverage-database/>. Accessibility verified September 27, 2017.
8. Remmers J, Charkhandeh S, Grosse J, et al. Remotely controlled mandibular protrusion during sleep predicts therapeutic success with oral appliances in patients with obstructive sleep apnea. *Sleep*. 2013;36(10):1517-1525.
9. Sutherland K, Ngiam J, Cistulli PA. Performance of remotely controlled mandibular protrusion sleep studies for prediction of oral appliance treatment response. *J Clin Sleep Med*. 2017;13(3):411-417.
10. Vanderveken OM, Devolder A, Marklund M, et al. Comparison of a custom-made appliance and a thermoplastic oral appliance for the treatment of mild sleep apnea. *Am J Respir Crit Care Med*. 2008;178(2):197-202.
11. Verbruggen AE, Dieltjens M, Wouters K, et al. Prevalence of residual excessive sleepiness during effective oral appliance therapy for sleep-disordered breathing. *Sleep Med*. 2013 Dec 30. [Epub ahead of print]

ARCHIVED

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 ₂	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 ₂	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