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CLINICAL APPROPRIATENESS GUIDELINES

SLEEP DISORDER MANAGEMENT

Appropriate Use Criteria: Diagnostic and Treatment Management

Proprietary

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Description and Application of the Guidelines

The AIM Clinical Appropriateness Guidelines (hereinafter “the AIM 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 criteria for medical necessity determinations where possible. 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 health care
- To promote the most efficient and cost-effective use of services

The AIM 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 the AIM 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 the AIM 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.

General Clinical Guideline

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.

Abbreviations

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

HNS: Hypoglossal nerve stimulation

MRA: Mandibular repositioning appliance

MSLT: Multiple sleep latency testing

MWT: Maintenance of wakefulness testing

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

SLEEP DISORDER DIAGNOSTIC MANAGEMENT

Polysomnography and Home Sleep Apnea Testing

Coding

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Non-specific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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

General Information

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
- Nocturnal oxygen desaturation
- 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)

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 apnea 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 apnea studies may be indicated in some situations. Patients who are age 18 years or younger, have severe chronic obstructive pulmonary disease, advanced congestive heart failure, neuromuscular diseases, or cognitive impairment, are not suitable candidates for home sleep

apnea studies. Patients with sleep disorders other than OSA are also not suitable candidates for home sleep apnea 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 2 hours of recording during sleep.
- 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 of sleep (based on at least 2 hours of recording during sleep.
- The **respiratory event index** (REI) is the average number of apneic and hypopneic episodes per hour of recording time and is only applicable to home sleep apnea testing where actual sleep time may not be known.

For the purposes of this guideline, the terms AHI, RDI, and REI may be used interchangeably.

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

- 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 such as 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 PAP devices remains problematic. Adherence to therapy is defined by the Centers for Medicare & Medicaid Services (CMS) as use of PAP for at least 4 hours per night on 70% of nights during a consecutive 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) is considered not medically necessary.~~

Clinical Indications

Home (Unattended) Sleep Studies

Home sleep apnea 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 **not medically necessary** in all clinical scenarios.

Suspected OSA

The following criteria apply to individuals with no contraindication to a home sleep apnea study*. See list of contraindications to home sleep apnea studies.*

Home sleep apnea studies are considered medically necessary if the patient meets **ANY** of the following criteria and has no contraindication to a home sleep apnea study:

- Observed apneas during sleep
- A combination of **at least TWO of 5 criteria listed below**:
    - 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
    - Habitual snoring or gasping/choking episodes associated with awakenings
    - Treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications)
    - Obesity, defined as a body mass index (BMI) greater than 30 kg/m^2 or neck circumference greater than 17 inches in men or greater than 16 inches in women
    - Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease
- History of stroke (more than 30 days previously), transient ischemic attack, coronary artery disease, or sustained supraventricular tachycardic or bradycardic arrhythmias in patients who meet **ONE of 5 criteria listed above**

Established OSA – follow-up home sleep apnea studies

The following criteria apply to individuals with no contraindication to a home sleep apnea study*. See list of contraindications to home sleep apnea studies.*

A follow-up home sleep apnea study is considered medically necessary for a patient with an established diagnosis of OSA and no contraindication to a home sleep apnea study when **EITHER** of the following applies:

- To assess efficacy of surgery (including adenotonsillectomy or upper airway) or oral appliances/devices
- To reevaluate the diagnosis of OSA and need for continued CPAP if there is a significant weight loss (defined as 10% of body weight) since the most recent sleep study

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)

***The following criteria apply to individuals with a contraindication to a home sleep apnea study**. See list of contraindications to home sleep apnea studies.*

An in-lab sleep (attended) study is considered medically necessary if the patient meets **ANY** of the following criteria and has a contraindication to a home sleep apnea study:

- Observed apneas during sleep
- A combination of **at least TWO of 5 criteria listed below**:
    - 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
    - Habitual snoring or gasping/choking episodes associated with awakenings
    - Treatment-resistant hypertension (persistent hypertension in a patient taking three or more antihypertensive medications)
    - Obesity, defined as a body mass index (BMI) greater than 30 kg/m^2 or neck circumference greater than 17 inches in men or greater than 16 inches in women
    - Craniofacial or upper airway soft tissue abnormalities, including adenotonsillar hypertrophy, or neuromuscular disease
- History of stroke (more than 30 days previously), transient ischemic attack, coronary artery disease, or sustained tachycardic or bradycardic arrhythmias in patients who meet **ONE of 5 criteria listed above**

Suspected sleep disorder other than OSA

An in-lab supervised sleep study is considered medically necessary when there is suspicion of **ANY** of the following:

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

Established sleep disorder (OSA or other) – follow-up laboratory studies

See contraindications to home sleep apnea studies and contraindications to the use of APAP.

A follow-up in-lab sleep study is considered medically necessary for a patient with an established diagnosis of OSA if **ANY** of the following apply:

- To assess efficacy of surgery (~~including~~ adenotonsillectomy or upper airway surgery) or oral appliances/devices in a patient with a contraindication to a home sleep apnea study
- To reevaluate the diagnosis of OSA and need for continued CPAP if there is significant weight loss (defined as 10% of body weight) since the most recent sleep study in a patient with a contraindication to a home sleep apnea study
- To optimize device settings on one occasion following insertion of a hypoglossal or phrenic nerve stimulator

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

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

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 considered medically necessary if the patient meets **ANY** of the following criteria:

- Habitual snoring in association with at least **ONE** of the following:
    - Restless or disturbed sleep
    - Behavioral disturbance or learning disorders including deterioration in academic performance, attention deficit disorder, hyperactivity
    - Frequent awakenings
    - Enuresis (bedwetting)
    - Growth retardation or failure to thrive
- Excessive daytime somnolence or altered mental status not explained by other conditions
- Polycythemia not explained by other conditions
- Cor pulmonale not explained by other conditions
- Witnessed apnea with duration greater than 2 respiratory cycles
- Labored breathing during sleep
- Hypertrophy of the tonsils or adenoids in patients at significant surgical risk such that the exclusion of OSA would allow avoidance of surgery
- Suspected congenital central alveolar hypoventilation syndrome or sleep-related hypoventilation due to neuromuscular disease or chest wall deformities
- Clinical evidence of a sleep-related breathing disorder in infants who have experienced an apparent life-threatening event
- For exclusion of OSA in a patient who has undergone adenotonsillectomy for suspected OSA more than 8 weeks previously

- 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 considered medically necessary in **ANY** of the following scenarios:

- A patient with established OSA continues to exhibit persistent snoring or other symptoms of sleep disordered breathing despite PAP adherence as defined by CMS criteria (use of PAP for at least 4 hours per night on 70% of nights during a consecutive 30-day period)
- The patient has undergone adenotonsillectomy or other upper airway surgery more than 8 weeks previously for management of established OSA
- To reevaluate the diagnosis of OSA and need for continued PAP if there is significant weight loss (defined as 10% of body weight) since the most recent sleep study
- To 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
- 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

Contraindications

Contraindications to Home Sleep Apnea Studies

- Age 18 years or younger
- Moderate or severe chronic obstructive pulmonary disease (COPD): FEV1/FVC less than or equal to 0.7 and FEV1 less than 80% of predicted
- Moderate or severe congestive heart failure: New York Heart Association (NYHA) class III or IV
- Congestive heart failure with a history of ventricular fibrillation or sustained ventricular tachycardia in a patient who does not have an implanted defibrillator
- Cognitive impairment (inability to follow simple instructions) resulting in inability to apply the home sleep apnea testing equipment when another individual is not available to assist with this task
- Physical impairment resulting in inability to apply the home sleep apnea testing equipment when another individual is not available to assist with this task
- Diagnosis suspected or established for **ONE** of the following conditions:
    - Central sleep apnea
    - Narcolepsy
    - Idiopathic hypersomnia
    - Parasomnia except bruxism and somniloqui (sleep talking)
    - Nocturnal seizures
    - Periodic limb movement disorder (PLMD)—to support a suspicion of PLMD in this context, **ONE** of the following must be documented: pregnancy, renal failure, iron deficiency anemia, peripheral neuropathy, use of antidepressant or antipsychotic medications, or continued hypersomnia and clinical symptoms of PLMD after sleep disordered breathing is ruled out by home sleep apnea testing
- Previous technically suboptimal home sleep apnea study in **EITHER** of the following scenarios:

  - Two nights of study attempted but not completed because the reason for the suboptimal study on night one is likely to recur on night two
  - Two nights of study attempted, but the study remains suboptimal after 2 nights
- Previous 2-night home sleep apnea study did not diagnose OSA in a patient with ongoing clinical suspicion of OSA
- Patient is oxygen dependent for any reason
- History of stroke within the preceding 30 days
- Chronic opiate ~~narcotic~~ use~~,~~ when discontinuation is not an option. Diagnostic sleep testing for patients using opiate~~s narcotics~~ for acute self-limited conditions should ideally be deferred until the medications have been stopped
- Body mass index (BMI) greater than 33 kg/m^2 and elevated serum bicarbonate level above 28 mmol/L
- Established diagnosis of obesity hypoventilation syndrome defined as a body mass index (BMI) greater than 30 kg/m^2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology, or medications. Documentation of hypoventilation requires **EITHER** of the following:
  - Increase in arterial PCO2 (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes
  - Greater than 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

Contraindications to APAP

- Age 18 years or younger
- Congestive heart failure
- Moderate or severe c~~C~~hronic obstructive pulmonary disease: FEV1/FVC less than or equal to 0.7 and FEV1 less than 80% of predicted
- Chronic narcotic use
- Central sleep apnea (defined as having at least 50% central events or more than 5 central events per hour)
- Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis)
- Obesity hypoventilation syndrome defined as a body mass index (BMI) greater than 30 kg/m^2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology, or medications. Documentation of hypoventilation requires **EITHER** of the following:
  - Increase in arterial PCO2 (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes
  - Greater than 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

Exclusions

Home sleep apnea studies performed with Type IV devices as defined above are considered **not medically necessary** in all clinical scenarios.

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, Karippot 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. Baker-Smith CM, Isaiah A, Melendres MC, et al. Sleep-Disordered Breathing and Cardiovascular Disease in Children and Adolescents: A Scientific Statement From the American Heart Association. Journal of the American Heart Association. 2021;10(18):e022427.
4. 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.
5. 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.
6. Caples SM, Anderson WM, Calero K, et al. Use of polysomnography and home sleep apnea tests for the longitudinal management of obstructive sleep apnea in adults: an American Academy of Sleep Medicine clinical guidance statement. J Clin Sleep Med. 2021;17(6):1287-93.
7. 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.
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. 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.
10. 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.
11. Mysliwiec V, Martin JL, Ulmer CS, et al. The Management of Chronic Insomnia Disorder and Obstructive Sleep Apnea: Synopsis of the 2019 U.S. Department of Veterans Affairs and U.S. Department of Defense Clinical Practice Guidelines. Annals of internal medicine. 2020;172(5):325-36.
12. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2019;15(2):335–343.
13. 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. Gottlieb DJ, Punjabi NM. Diagnosis and Management of Obstructive Sleep Apnea: A Review. Jama. 2020;323(14):1389-400.
6. Ioachimescu OC, Allam JS, Samarghandi A, et al. Performance of peripheral arterial tonometry-based testing for the diagnosis of obstructive sleep apnea in a large sleep clinic cohort. J Clin Sleep Med. 2020;16(10):1663-74.
7. 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.
8. 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.
9. 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.
10. 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.

11. Sarkissian L, Kitipornchai L, Cistulli P, et al. An update on the current management of adult obstructive sleep apnoea. Aust J Gen Pract. 2019;48(4):182-6.
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.
13. 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 and Maintenance of Wakefulness Testing

Coding

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Non-specific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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

General Information

Scope of the Guideline

This guideline is applicable to the 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.

Clinical Indications

Multiple Sleep Latency Testing and Maintenance of Wakefulness Testing

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

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

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

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

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

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

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

- Daytime hypersomnolence has been present for at least 8 weeks
- The patient has at least **ONE** of the following:
    - Difficult morning awakening
    - Prolonged ~~night~~ sleep during primary sleep period
    - Sleep drunkenness
    - Frequent non-refreshing daytime naps
    - The patient has undergone ~~polysomnography since the onset of symptoms (~~PSG or HSAT)~~ ~~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. Krahn LE, Arand DL, Avidan AY, et al. Recommended protocols for the Multiple Sleep Latency Test and Maintenance of Wakefulness Test in adults: guidance from the American Academy of Sleep Medicine. J Clin Sleep Med. 2021.
3. 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.
4. 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.

SLEEP DISORDER TREATMENT MANAGEMENT

Management of Obstructive Sleep Apnea using Auto-Titrating and Continuous Positive Airway Pressure Devices

Coding

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Non-specific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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

General Information

Scope of the Guideline

This guideline is applicable to the 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 guideline addresses the use of bi-level positive airway pressure (BPAP).

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 such as sleeping position, sleep stage, 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 for at least 4 hours per night on 70% of nights during a consecutive 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) is considered not medically necessary.~~

Clinical Indications

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

Treatment with CPAP is considered medically necessary for a patient aged 19 years or older when BOTH of the following criteria are met:

For contraindications to the use of APAP, see APAP contraindications.

- Home- or lab-based sleep study demonstrates **ONE** of the following:
  - AHI 15 or higher
  - AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, history of stroke
- Appropriate CPAP level has been determined from **ONE** of the following:
  - Split-night sleep study
  - Whole-night lab-based titration study following a diagnostic lab study at which the CPAP level was not determined
  - Whole-night lab-based titration study in a patient for whom APAP is contraindicated (see APAP contraindications)

- APAP titration trial
- Whole-night lab-based titration study when home, unmonitored APAP titration was unsuccessful

Treatment with CPAP is considered medically necessary for a patient aged 18 years or younger when BOTH of the following criteria are met:

- A lab-based sleep study demonstrating AHI of at least 1 (one) and appropriate CPAP titration has been performed
- **ONE** of the following is true:
  - Adenotonsillectomy has been unsuccessful in curing OSA
  - Adenotonsillectomy is not indicated because the patient has minimal adenotonsillar tissue
  - Adenotonsillectomy is inappropriate because OSA is attributable to another underlying cause (e.g., craniofacial abnormality, morbid obesity)
  - Adenotonsillectomy is contraindicated

Treatment with APAP is considered medically necessary when BOTH of the following criteria are met:

- Home or lab-based sleep study demonstrates **ONE** of the following:
  - AHI 15 or higher
  - AHI 5–14 with any of the following: excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease, history of stroke
- **EITHER** of the following:
  - The patient has no contraindication to the use of APAP (see APAP contraindications)
  - In the opinion of the treating provider, APAP is preferable to in-lab titration

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

Ongoing treatment with APAP or CPAP is considered medically necessary 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 **EITHER** of the following:

- Use of the CPAP device for at least 4 hours per night on 70% of nights during a consecutive 30-day period within the preceding 90 days
- Clinical evidence that demonstrates continued clinical benefit from use of the PAP device is submitted by the treating provider

Contraindications

Contraindications to APAP

- Age 18 years or younger
- Congestive heart failure
- Moderate or severe chronic obstructive pulmonary disease (COPD): FEV1/FVC less than or equal to 0.7 and FEV1 less than 80% of predicted ~~Chronic obstructive pulmonary disease~~
- Chronic opiate ~~narcotic~~ use

- Central sleep apnea (defined as having at least 50% central events or more than 5 central events per hour)
- Neuromuscular disorders (e.g., muscular dystrophy, myasthenia gravis)
- Obesity hypoventilation syndrome defined as a body mass index (BMI) greater than 30 kg/m^2 and hypoventilation which cannot be solely attributed to other conditions such as pulmonary disease, skeletal restriction, neuromuscular weakness, hypothyroidism, pleural pathology, or medications. Documentation of hypoventilation requires **EITHER** of the following:
    - Increase in arterial PCO2 (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes
    - Greater than 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

Exclusions

Positive airway pressure treatment modalities and add-on devices not addressed in this guideline (including but not limited to PapNap, Provent, headstraps, certain dental devices, and Weaver's masks cloths), reported using CPT code E1399, are considered **not medically necessary**.

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.
2.3. Balk EM, Adam GP, Cao W, et al. Long-Term Health Outcomes in Obstructive Sleep Apnea: A Systematic Review of Comparative Studies Evaluating Positive Airway Pressure and Validity of Breathing Measures as Surrogate Outcomes. Project ID: SLPT0919. December 2022 ed. Rockville, MD: Agency for Healthcare Research and Quality; 2022. p. 182.
3.4. 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.
5. 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.
4.6. Chang JL, Goldberg AN, Alt JA, et al. International consensus statement on obstructive sleep apnea. International forum of allergy & rhinology. 2022.
5.7. 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.
6.8. 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.
9. 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.
7.10. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Journal of the American College of Cardiology. 2022;79(17):e263-e421.
8.11. Kent D, Stanley J, Aurora RN, et al. Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021.
9.12. Li P, Ning XH, Lin H, et al. Continuous positive airway pressure versus mandibular advancement device in the treatment of obstructive sleep apnea: a systematic review and meta-analysis. Sleep medicine. 2020;72:5-11.
10.13. 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.

~~11.~~14. Mokhlesi B, Masa JF, Brozek JL, et al. Evaluation and Management of Obesity Hypoventilation Syndrome. An Official American Thoracic Society Clinical Practice Guideline. American journal of respiratory and critical care medicine. 2019;200(3):e6-e24.

~~12.~~15. 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.

~~13.~~16. Mysliwiec V, Martin JL, Ulmer CS, et al. The Management of Chronic Insomnia Disorder and Obstructive Sleep Apnea: Synopsis of the 2019 U.S. Department of Veterans Affairs and U.S. Department of Defense Clinical Practice Guidelines. Annals of internal medicine. 2020;172(5):325-36.

~~14.~~17. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2019;15(2):335–343.

~~15.~~18. 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.

~~16.~~19. Timkova V, Nagyova I, Reijneveld SA, et al. Quality of life of obstructive sleep apnoea patients receiving continuous positive airway pressure treatment: A systematic review and meta-analysis. Heart & lung : the journal of critical care. 2020;49(1):10-24.

~~17.~~20. Trzepizur W, Cistulli PA, Glos M, et al. Health outcomes of continuous positive airway pressure versus mandibular advancement device for the treatment of severe obstructive sleep apnea: an individual participant data meta-analysis. Sleep. 2021;44(7):09.

~~18.~~21. 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.

~~19.~~22. 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.

~~20.~~23. Zhang M, Liu Y, Liu Y, et al. Effectiveness of oral appliances versus continuous positive airway pressure in treatment of OSA patients: An updated meta-analysis. Cranio. 2019;37(6):347-64.

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, Başyiğit 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. Masa JF, Mokhlesi B, Benitez I, et al. Long-term clinical effectiveness of continuous positive airway pressure therapy versus non-invasive ventilation therapy in patients with obesity hypoventilation syndrome: a multicentre, open-label, randomised controlled trial. Lancet (London, England). 2019;393(10182):1721-32.
8. 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.
9. Ozsancak A, D'Ambrosio C, Hill NS. Nocturnal noninvasive ventilation. Chest. 2008;133(5):1275-1286.
10. 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.
11. 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.
12. 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.
13. 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.
14. Uniken Venema JAM, Doff MHJ, Joffe-Sokolova D, et al. Long-term obstructive sleep apnea therapy: a 10-year follow-up of mandibular advancement device and continuous positive airway pressure. J Clin Sleep Med. 2020;16(3):353-9.

Bi-Level Positive Airway Pressure Devices

Coding

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Non-specific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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

General Information

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.

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 for at least 4 hours per night on 70% of nights during a consecutive 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) is considered not medically necessary.~~

Clinical Indications

Bi-Level Positive Airway Pressure (BPAP) Devices

BPAP (without back-up rate feature)

BPAP without back-up rate feature is considered medically necessary for patients with OSA who have failed CPAP/APAP or require supplemental ventilatory support due to a hypoventilation syndrome

BPAP (with or without back-up rate feature) for patients with established CSA

BPAP with or without back-up rate feature is considered medically necessary for patients with established CSA diagnosed by an in-lab sleep study when **BOTH** of the following apply:

- OSA has been excluded or treated
- 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 greater than 45%.

BPAP (with or without back-up rate feature) for patients with severe COPD

BPAP with or without back-up rate feature is considered medically necessary in the management of patients with severe COPD demonstrating **EITHER** of the following:

- $PaCO_2$ measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO_2 is 52 mmHg or greater
- 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_2 (whichever is higher)

BPAP (with or without back-up rate feature) for patients with certain restrictive thoracic disorders

BPAP with or without back-up rate feature is considered medically necessary in the management of patients with certain restrictive thoracic disorders when **BOTH** of the following are true:

- The patient has an established diagnosis of a progressive neuromuscular disease, e.g., amyotrophic lateral sclerosis (ALS), or a severe thoracic cage abnormality
- **ONE** of the following statements is true:
    - $PaCO_2$ measured by arterial blood gas drawn while the patient is awake and breathing his/her usual FiO_2 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_2
    - Maximal inspiratory pressure is less than 60 cm H_2O or forced vital capacity is less than 50% of predicted (applies to patients with progressive neuromuscular disease only)

BPAP (with or without back-up rate feature) for patients with obesity hypoventilation syndrome

Obesity Hypoventilation Syndrome (OHS) defined as a body mass index (BMI) greater than 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.

Ongoing treatment with BPAP

Ongoing treatment with BPAP for obstructive sleep apnea * is considered medically necessary for adult patients who demonstrate compliance with therapy. Demonstration of compliance is required for adult patients every 90 days for the first year of treatment and annually thereafter. Compliance is defined as **EITHER** of the following:

- Use of the BPAP device for at least 4 hours per night on 70% of nights during a consecutive 30-day period within the preceding 90 days
- Clinical evidence that demonstrates continued clinical benefit from use of the PAP device is submitted by the treating provider

*Demonstration of compliance is not required for non-adult patients or when BPAP is used for disordes other than OSA and CSA

Exclusions

Positive airway pressure treatment modalities and add-on devices not addressed in this guideline (including but not limited to PapNap, Provent, headstraps, certain dental devices, and Weaver's masks cloths), reported using CPT code E1399, are considered **not medically necessary**.

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. Gantzhorn EK, Prior TS, Hilberg O. Long-term non-invasive ventilation for stable chronic hypercapnic COPD. European clinical respiratory journal. 2019;6(1):1644893. Epub 2019/08/27. PMID: 31448069
7. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease 2019 Report. Fontana, WI (USA): Global Initiative for Chronic Obstructive Lung Disease, Inc.; 2019. p. 155.
8. 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.
9. 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.
10. McDonagh TA, Metra M, Adamo M, et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. European heart journal. 2021;42(36):3599-726.
~~10.~~11. National Institute for Health and Care Excellence (NICE). Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s NICE guideline [NG202]. London (UK): National Institute for Health and Care Excellence; 2021. p. 100.
~~11.~~12. Royer CP, Schweiger C, Manica D, et al. Efficacy of bilevel ventilatory support in the treatment of stable patients with obesity hypoventilation syndrome: systematic review and meta-analysis. Sleep medicine. 2019;53:153-64.
~~12.~~13. Soghier I, Brozek JL, Afshar M, et al. Noninvasive Ventilation versus CPAP as Initial Treatment of Obesity Hypoventilation Syndrome. Annals of the American Thoracic Society. 2019;16(10):1295-303.
14. 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.~~15. Xu J, Wei Z, Li W, et al. Effect of different modes of positive airway pressure treatment on obesity hypoventilation syndrome: a systematic review and network meta-analysis. Sleep medicine. 2022;91:51-8.

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. Murphy PB, Rehal S, Arbane G, et al. Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation: A Randomized Clinical Trial. JAMA. 2017;317(21):2177-86. Epub 2017/05/22. PMID: 28528348
5. Ozsancak A, D'Ambrosio C, Hill NS. Nocturnal noninvasive ventilation. Chest. 2008;133(5):1275-1286.
6. Struik FM, Sprooten RT, Kerstjens HA, et al. Nocturnal non-invasive ventilation in COPD patients with prolonged hypercapnia after ventilatory support for acute respiratory failure: a randomised, controlled, parallel-group study. Thorax. 2014;69(9):826-34. Epub 2014/05/02. PMID: 24781217

Management of Obstructive Sleep Apnea using Oral Appliances

Coding

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Non-specific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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

D9947..... Custom sleep apnea appliance fabrication and placement

D9948..... Adjustment of custom sleep apnea appliance

K1027..... Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment

General Information

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 guideline 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 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 oral appliances 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 oral appliance rather than PAP as a first line therapy. It is highly recommended that the decision to use an oral appliance 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 & 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.

Clinical Indications

Custom Fabricated Oral Appliances (CPT E0486)

Treatment with an Oral Appliance is considered medically necessary for patients aged 16 years or older with severe OSA (apnea/hypopnea index [AHI] greater than 30) when BOTH of the following criteria are met:

- The appliance is a TRD or a Medicare-compliant MRA
- **ONE** of the following:
    - Patient is not a candidate for PAP therapy
    - PAP therapy has not been effective despite a 45-day trial and participation in a PAP compliance program
    - Patient has tried CPAP but has not been compliant despite a 45-day trial and participation in a PAP compliance program

Treatment with an Oral Appliance is considered medically necessary for patients aged 16 years or older with mild or moderate OSA when ALL of the following criteria are met:

- The appliance is a TRD or a Medicare-compliant MRA
- **ONE** of the following:
    - AHI 15–30
    - 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
- **ONE** of the following:
    - Patient is not a candidate for PAP therapy
    - PAP therapy has not been effective despite a 45-day trial and participation in a PAP compliance program
    - Patient has tried CPAP but has not been compliant despite a 45-day trial and participation in a PAP compliance program
    - Patient prefers to use an oral appliance rather than PAP as the initial therapy

Exclusions

Prefabricated oral appliances (CPT E0485)

Prefabricated oral appliances are considered **not medically necessary** for obstructive sleep apnea in all clinical scenarios

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. Carvalho FR, Lentini-Oliveira DA, Prado LB, et al. Oral appliances and functional orthopaedic appliances for obstructive sleep apnoea in children. Cochrane Database Syst Rev. 2016;10(10):Cd005520.
3. 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.
4. 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.
5. Ilea A, Timus D, Hopken J, et al. Oral appliance therapy in obstructive sleep apnea and snoring - systematic review and new directions of development. Cranio. 2019:1-12.
6. 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.
6.7. National Institute for Health and Care Excellence (NICE). Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s NICE guideline [NG202]. London (UK): National Institute for Health and Care Excellence; 2021. p. 100.
7.8. 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.
8.9. Trzepizur W, Cistulli PA, Glos M, et al. Health outcomes of continuous positive airway pressure versus mandibular advancement device for the treatment of severe obstructive sleep apnea: an individual participant data meta-analysis. Sleep. 2021;44(7).
9.10. Zhang M, Liu Y, Liu Y, et al. Effectiveness of oral appliances versus continuous positive airway pressure in treatment of OSA patients: An updated meta-analysis. Cranio. 2019;37(6):347-64.

Other Literature

1. de Vries GE, Hoekema A, Claessen J, et al. Long-Term Objective Adherence to Mandibular Advancement Device Therapy Versus Continuous Positive Airway Pressure in Patients With Moderate Obstructive Sleep Apnea. J Clin Sleep Med. 2019;15(11):1655-63.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
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. Uniken Venema JAM, Doff MHJ, Joffe-Sokolova D, et al. Long-term obstructive sleep apnea therapy: a 10-year follow-up of mandibular advancement device and continuous positive airway pressure. J Clin Sleep Med. 2020;16(3):353-9.
11. 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.
12. 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].

Management of Obstructive Sleep Apnea using Implanted Hypoglossal Nerve Stimulators

Coding

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Non-specific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

64582 ..... Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

64583 ..... Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator

64584 ..... Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

C1767..... Generator, neurostimulator (implantable), nonrechargeable [when specified as a component of an HNS]

General Information

Scope of the Guideline

This guideline is applicable to use of hypoglossal nerve stimulation in the management of obstructive sleep apnea (OSA). Hypoglossal nerve stimulation (HNS) is provided by a programmable, surgically implanted subcutaneous device connected to an electrode which carries electrical impulses to the hypoglossal nerve in the submental area. Hypoglossal nerve stimulation results in forward movement of the tongue and increase in upper airway tone such that upper airway patency is maintained during sleep. Stimulation can be timed to inspiration (using a sensor to detect respiration) and the device can be turned off (using the external controller) while the patient is awake.

Overview

In addition to lifestyle changes (weight loss, avoidance of alcohol and sedatives, etc.), positive airway pressure (PAP) therapy is considered the first-line approach in the management of adult patients with all degrees of obstructive sleep apnea. However, long-term compliance with PAP therapy is poor and even for users who are complaint, find PAP therapy to be cumbersome and inconvenient. Currently there is only one HNS device with FDA approval for management of OSA. Since the publication of the STAR trial in 2014 there have been several further studies demonstrating that HNS results in subjective and objective improvement in OSA. However, as with PAP treatment for OSA, evidence of improvement in objective patient outcomes (mortality, myocardial infarction, stroke, hypertension, etc.) is more difficult to find.

Patient selection is important because the therapy is invasive (compared to PAP and oral appliances), and not universally appropriate. HNS devices are more costly than other therapies and devices need to be replaced approximately every decade. Complications related to device insertion are uncommon, but some patients are intolerant of HNS.

Definitions

Failure of PAP therapy: AHI greater than 15 when the patient is using PAP for more than 4 hours per night on 70% of nights

Intolerance of PAP therapy: Inability or unwillingness to use PAP for more than 4 hours per night on 70% of nights

Drug-induced sleep endoscopy: Upper airway endoscopy performed during pharmacologically induced sleep

Clinical Indications

Treatment with HNS is considered medically necessary for adult patients with OSA who meet ALL of the following criteria:

- Age 18 years or older
- AHI or RDI is 15–65 with less than 25% central events
- Body mass index (BMI) less than or equal to 32 kg/m^2
- Have failed or are intolerant of PAP therapy
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy

Treatment with HNS is considered medically necessary for adolescent and young adult patients with Down syndrome and OSA who meet ALL of the following criteria:

- Age between 10 and 21 years
- AHI or RDI between 10 and 50 with less than 25% central apneas after prior adenotonsillectomy
- Body mass index (BMI) less than or equal to the 95th percentile for age
- Have either had tracheotomy or been ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device
- Non-concentric retropalatal obstruction on drug-induced sleep endoscopy

References

Specialty Society Guidelines and Systematic Reviews

1. Certal VF, Zaghi S, Riaz M, et al. Hypoglossal nerve stimulation in the treatment of obstructive sleep apnea: A systematic review and meta-analysis. Laryngoscope. 2015;125(5):1254-64.
2. Chang JL, Goldberg AN, Alt JA, et al. International consensus statement on obstructive sleep apnea. International forum of allergy & rhinology. 2022.
3. European Network for Health Technology Assessment (EUnetHTA) OTCA21 Authoring Team. Hypoglossal Nerve Stimulation Systems for Treatment of Obstructive Sleep Apnea: Project ID: OTCA21. Diemen (The Netherlands): EUnetHTA; 2020. p. 90.
4. Halle TR, Oh MS, Collop NA, et al. Surgical Treatment of OSA on Cardiovascular Outcomes: A Systematic Review. Chest. 2017;152(6):1214-29.
5. National Institute for Health and Care Excellence (NICE). Hypoglossal Nerve Stimulation for Moderate to Severe Obstructive Sleep Apnea, Interventional Procedure Guidance IPG598. United Kingdom: National Institute for Health and Care Excellence (NICE); 2017. p. 47.
6. Randerath W, Verbraecken J, de Raaff CAL, et al. European Respiratory Society guideline on non-CPAP therapies for obstructive sleep apnoea. Eur. 2021;30(162):31.

Other Literature

1. Bowen AJ, Nowacki AS, Kominsky AH, et al. Voice and swallowing outcomes following hypoglossal nerve stimulation for obstructive sleep apnea. Am J Otolaryngol. 2018;39(2):122-6.

2. Caloway CL, Diercks GR, Keamy D, et al. Update on hypoglossal nerve stimulation in children with down syndrome and obstructive sleep apnea. Laryngoscope. 2020;130(4):E263-E7.
3. Diercks GR, Wentland C, Keamy D, et al. Hypoglossal Nerve Stimulation in Adolescents With Down Syndrome and Obstructive Sleep Apnea. JAMA Otolaryngol Head Neck Surg. 2018;144(1):37-42. Epub 2017/11/04.
4. Friedman M, Jacobowitz O, Hwang MS, et al. Targeted hypoglossal nerve stimulation for the treatment of obstructive sleep apnea: Six-month results. Laryngoscope. 2016;126(11):2618-23.
5. Gillespie MB, Soose RJ, Woodson BT, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Patient-Reported Outcomes after 48 Months of Follow-up. Otolaryngol Head Neck Surg. 2017;156(4):765-71.
6. Heiser C, Edenharter G, Bas M, et al. Palatoglossus coupling in selective upper airway stimulation. Laryngoscope. 2017;127(10):E378-E83.
7. Heiser C, Knopf A, Bas M, et al. Selective upper airway stimulation for obstructive sleep apnea: a single center clinical experience. European Archives of Oto-Rhino-Laryngology. 2017;274(3):1727-34.
8. Heiser C, Maurer JT, Hofauer B, et al. Outcomes of Upper Airway Stimulation for Obstructive Sleep Apnea in a Multicenter German Postmarket Study. Otolaryngol Head Neck Surg. 2017;156(2):378-84.
9. Heiser C, Maurer JT, Steffen A. Functional outcome of tongue motions with selective hypoglossal nerve stimulation in patients with obstructive sleep apnea. Sleep Breath. 2016;20(2):553-60.
10. Hofauer B, Philip P, Wirth M, et al. Effects of upper-airway stimulation on sleep architecture in patients with obstructive sleep apnea. Sleep Breath. 2017;21(4):901-8.
11. Huntley C, Steffen A, Doghramji K, et al. Upper Airway Stimulation in Patients With Obstructive Sleep Apnea and an Elevated Body Mass Index: A Multi-institutional Review. Laryngoscope. 2018;128(10):2425-8. Epub 2018/08/12.
12. Kezirian EJ, Goding GS, Jr., Malhotra A, et al. Hypoglossal nerve stimulation improves obstructive sleep apnea: 12-month outcomes. Journal of sleep research. 2014;23(1):77-83.
13. Lorenzi-Filho G, Almeida FR, Strollo PJ. Treating OSA: Current and emerging therapies beyond CPAP. Respirology. 2017;22(8):1500-7.
14. Mahmoud AF, Thaler ER. Upper airway stimulation therapy and prior airway surgery for obstructive sleep apnea. Laryngoscope. 2018;128(6):1486-9.
15. Mwenge GB, Rombaux P, Dury M, et al. Targeted hypoglossal neurostimulation for obstructive sleep apnoea: a 1-year pilot study. Eur Respir J. 2013;41(2):360-7. Epub 2012/05/19.
16. Parikh V, Thaler E, Kato M, et al. Early feasibility of hypoglossal nerve upper airway stimulator in patients with cardiac implantable electronic devices and continuous positive airway pressure-intolerant severe obstructive sleep apnea. Heart Rhythm. 2018;15(8):1165-70.
17. Safiruddin F, Vanderveken OM, de Vries N, et al. Effect of upper-airway stimulation for obstructive sleep apnoea on airway dimensions. Eur Respir J. 2015;45(1):129-38.
18. Schwartz AR, Barnes M, Hillman D, et al. Acute upper airway responses to hypoglossal nerve stimulation during sleep in obstructive sleep apnea. Am J Respir Crit Care Med. 2012;185(4):420-6.
19. Shah J, Russell JO, Waters T, et al. Uvulopalatopharyngoplasty vs CN XII stimulation for treatment of obstructive sleep apnea: A single institution experience. Am J Otolaryngol. 2018;39(3):266-70.
20. Soose RJ, Gillespie MB. Upper airway stimulation therapy: A novel approach to managing obstructive sleep apnea. Lancet (London, England). 2016;126 Suppl 7:S5-8. Epub 2016/09/07.
21. Soose RJ, Woodson BT, Gillespie MB, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Self-Reported Outcomes at 24 Months. J Clin Sleep Med. 2016;12(1):43-8.
22. Steffen A, Kilic A, Konig IR, et al. Tongue motion variability with changes of upper airway stimulation electrode configuration and effects on treatment outcomes. Laryngoscope. 2018;128(8):1970-6.
23. Steffen A, Sommer JU, Hofauer B, et al. Outcome after one year of upper airway stimulation for obstructive sleep apnea in a multicenter German post-market study. Laryngoscope. 2018;128(2):509-15.
24. Stenerson ME, Yu PK, Kinane TB, et al. Long-term stability of hypoglossal nerve stimulation for the treatment of obstructive sleep apnea in children with Down syndrome. Int J Pediatr Otorhinolaryngol. 2021;149:110868.
25. Strollo PJ, Jr., Gillespie MB, Soose RJ, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: Durability of the Treatment Effect at 18 Months. Sleep. 2015;38(10):1593-8.
26. Strollo PJ, Jr., Soose RJ, Maurer JT, et al. Upper-airway stimulation for obstructive sleep apnea. N Engl J Med. 2014;370(2):139-49.
27. Van de Heyning PH, Badr MS, Baskin JZ, et al. Implanted upper airway stimulation device for obstructive sleep apnea. Laryngoscope. 2012;122(7):1626-33.
28. Woodson BT, Gillespie MB, Soose RJ, et al. Randomized controlled withdrawal study of upper airway stimulation on OSA: short- and long-term effect. Otolaryngol Head Neck Surg. 2014;151(5):880-7.

29. Woodson BT, Soose RJ, Gillespie MB, et al. Three-Year Outcomes of Cranial Nerve Stimulation for Obstructive Sleep Apnea: The STAR Trial. Otolaryngol Head Neck Surg. 2016;154(1):181-8.
30. Woodson BT, Strohl KP, Soose RJ, et al. Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes. Otolaryngol Head Neck Surg. 2018;159(1):194-202. Epub 2018/03/28.
31. Zhu Z, Hofauer B, Wirth M, et al. Selective upper airway stimulation in older patients. Respir Med. 2018;140:77-81.

History

Status	Review Date	Effective Date	Action
Revised	1/24/2023		Independent Multispecialty Physician Panel (IMPP) review. Changed home sleep study/test to home sleep apnea study/test; added indication for one time optimization of phrenic nerve simulator after insertion; specified that APAP is contraindicated for moderate to severe COPD; added BPAP indication for patients with OHS; clarified demonstration of PAP compliance is not required for non-adult patients or patients using BPAP for disorders other than OSA or CSA; clarified that medical necessity of MSLT/MWT can be satisfied with either preceding PSG or HSAT; idiopathic hypersomnia prerequisite modified from "prolonged night sleep" to "prolonged sleep during primary sleep period". Added references.
Updated	–	02/11/2023	Added CPT codes D9947 and D9948.
Revised	11/11/2021	09/11/2022	Independent Multispecialty Physician Panel (IMPP) review. Established sleep disorder (OSA or other): added indication for one follow-up in-lab sleep study as appropriate following insertion of a hypoglossal nerve stimulator (HNS); revised definition of PAP therapy adherence per CMS criteria. New indication for MWT in occupational safety evaluation. Management of OSA using oral appliances limited to patients aged ≥16 years. New guideline for management of OSA using implanted hypoglossal nerve stimulators (added CPT/HCPCS codes 64582, 64583, 64584, C1767). Added references.
Reaffirmed	12/03/2020	Unchanged	IMPP review. Updated references. Guideline reaffirmed.
Revised	10/29/2019	08/16/2020	IMPP review. Changed FiO2 level to 52 mmHg for patients with severe COPD in indication for BPAP. Added references.
Revised	06/10/2019	02/09/2020	IMPP review. Added chronic narcotic use as a contraindication to APAP. Expanded treatment of mild OSA with APAP and CPAP to patients with any hypertension.
Revised	11/28/2018	06/29/2019	IMPP review. Revised structure of BPAP with and without back-up rate feature criteria for patients with established central sleep apnea (CSA). Removed the criteria to try rate support for CSA.
Revised	07/11/2018	03/09/2019	IMPP review. Added the General Clinical Guideline.
Revised	04/12/2018	01/27/2019	Removed HCPCS code A7047 and references to the ApniCure Winx device, which is no longer available.
Revised	09/07/2017	11/20/2017	IMPP review. Added requirements for documentation for conditions supporting a diagnosis of periodic limb movement disorder, and for BPAP without backup rate has been attempted, but has not successfully treated episodes of desaturation. Amended use of BPAP in patients with CSA and reduced left ventricular function to apply only to BPAP when used in ASV mode. Added obesity hypoventilation syndrome as contraindication to APAP.
Created	05/04/2012	07/01/2012	Original effective date.