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Status: Revised
Effective Date: 11/15/2025
Doc ID: SDM01-1125.1
Last Review Date: 01/30/2025

Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Sleep Disorder Management

Appropriate Use Criteria: Diagnostic and Treatment Management

Proprietary
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Table of Contents

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Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon 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. The Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible, that can be used in support of the following:

- 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 address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal 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. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon 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 Carelon 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, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there is not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon 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.

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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 is likely to outweigh any potential harms, including from delay or decreased access to serviced that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

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 justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

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

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- 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. Requests for ongoing services may depend on completion of previously authorized services in situations where a patient's response to authorized serviced is relevant to a determination of clinical appropriateness.

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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

HSAT: Home sleep apnea study

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

RLS: Restless Leg Syndrome

TRD: Tongue retaining device

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SLEEP DISORDER DIAGNOSTIC MANAGEMENT

Polysomnography and Home Sleep Apnea Testing

General Information

Guideline Scope

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.

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Sleep testing may be classified as follows:

- **Type I**: An attended sleep study performed in a hospital or freestanding sleep lab with continuous and simultaneous monitoring of electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (EKG), electromyogram (EMG), oxygen saturation, respiratory effort, and airflow. Type I studies are also known as polysomnography (PSG).
- **Type II**: A sleep study (usually unattended) performed with portable equipment with continuous and simultaneous monitoring of EEG, EOG, EKG, EMG, oxygen saturation, respiratory effort, and airflow. Type II studies are similar to type I (PSG) studies except that the former are usually performed in the home.
- **Type III**: An unattended sleep study performed with portable equipment with monitoring of a minimum of four channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation. The studies are performed in the home and differ from types I and II in that they do not provide data on sleep staging.
- **Type IV**: An unattended sleep study performed with portable equipment with monitoring of three or fewer physiological parameters only one of which is airflow. The studies are performed in the home and differ from types I and II in that they do not provide data on sleep staging.

Portable testing units that provide respiratory analysis through measurement of peripheral arterial tone (which do not fit neatly into the above classification) are an alternative approach to HSAT. 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 17 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 18 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

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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.

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

Home sleep apnea studies are considered medically necessary if the patient meets **ANY** of the following criteria:

- 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**

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- Any of the following conditions which may suggest OSA when the etiology is unclear: right heart failure, polycythemia, sustained supraventricular or ventricular tachyarrhythmia occurring solely during sleep, or pulmonary hypertension

Established OSA – follow-up home sleep apnea studies

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

- On one occasion following:
  - Upper airway surgery performed to treat OSA and/or improve compliance with PAP therapy
  - Initiation of use of an oral appliance
- 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
- Prior to implantation of a hypoglossal nerve stimulator in a patient who has not had a diagnostic study (home or lab) within the preceding 18 months

In-Lab (Attended) Sleep Studies in Adult Patients (Age 18 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**
- Any of the following conditions which may suggest OSA when the etiology is unclear: right heart failure, polycythemia, cardiac sustained supraventricular or ventricular tachyarrhythmia occurring solely during sleep, or pulmonary hypertension

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:

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- Central sleep apnea (CSA) – to support the suspicion of CSA in this context, **ONE** of the following must be documented: heart failure, stroke within the preceding 90 days, chronic opiate or narcotic use or Chiari malformation. OSA should be excluded before considering CSA in patients who snore.
- Narcolepsy
- Nocturnal seizures
- Parasomnia which is likely to result in harm to the patient or others
- 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. A diagnosis of PLMD requires that the patient have ongoing hypersomnia or insomnia, Patients with OSA and/or RLS should have these conditions treated before evaluation for PLMD.
- Nocturnal desaturation (due to severe COPD or certain restrictive thoracic disorders)

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:

- On one occasion following:
    - Upper airway surgery performed to treat OSA and/or improve compliance with PAP therapy in a patient with a contraindication to a HSAT
    - Initiation of use of an oral appliance in a patient with a contraindication to a HSAT
- 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
- Prior to implantation of a hypoglossal nerve stimulator in a patient who has no contraindication to a HSAT and has not had a diagnostic study (home or lab) within the preceding 18 months
- 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 17 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:

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- 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
- Prior to implantation of a hypoglossal nerve stimulator in a patient who has not had a diagnostic study (home or lab) within the preceding 18 months
- 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

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Contraindications

Contraindications to Home Sleep Apnea Studies

- Age 17 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 use when discontinuation is not an option. Diagnostic sleep testing for patients using opiates 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 **ANY** of the following:
    - Increase in arterial $PaCO_2$ (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes

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- Greater than 10 mmHg increase in arterial $PaCO_2$ (or surrogate measure) during sleep (compared to an awake supine value) to a value exceeding 50 mmHg for at least 10 minutes
- Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 consecutive minutes of nocturnal recording time (minimum recording time of 2 hours), recorded while breathing the patient's prescribed FiO_2

Contraindications to APAP

- Congestive heart failure
- Moderate or severe chronic obstructive pulmonary disease: FEV1/FVC less than or equal to 0.7 and FEV1 less than 80% of predicted
- Chronic opiate use
- Use of supplemental oxygen for 24 hours daily
- 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 **ANY** of the following:
  - Increase in arterial $PaCO_2$ (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes
  - Greater than 10 mmHg increase in arterial $PaCO_2$ (or surrogate measure) during sleep (compared to an awake supine value) to a value exceeding 50 mmHg for at least 10 minutes
  - Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 consecutive minutes of nocturnal recording time (minimum recording time of 2 hours), recorded while breathing the patient's prescribed FiO_2

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. Cagle JL, Young BD, Shih MC, et al. Portable Sleep Study Device Versus Polysomnography: A Meta-analysis. Otolaryngol Head Neck Surg. 2023;168(5):944-55.

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6. 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.
7. 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.
8. 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.
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.
10. 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.
11. Mangione CM, Barry MJ, Nicholson WK, et al. Screening for Obstructive Sleep Apnea in Adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2022;328(19):1945-50.
12. 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.
13. 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. 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. 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.

Codes

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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

Multiple Sleep Latency Testing and Maintenance of Wakefulness Testing

General Information

Guideline Scope

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.

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Idiopathic hypersomnia

Daytime sleepiness following adequate (or even prolonged) nocturnal sleep duration and non-refreshing daytime naps are characteristic of idiopathic hypersomnia. Patients with idiopathic hypersomnia may have sleep paralysis and hallucination but cataplexy is absent. Despite prolonged sleep duration, patients with idiopathic hypersomnia display difficult morning awakening, sleep drunkenness and constant somnolence. Idiopathic hypersomnia is rarer than narcolepsy and tends to be more resistant to treatment. A diagnosis of idiopathic hypersomnia requires exclusion of other causes of fatigue and excessive daytime sleepiness including hypothyroidism, depression, obstructive sleep apnea, etc. Patients who have undergone diagnostic testing for OSA and whose AHI is >5 should be adequately treated for OSA before undergoing evaluation for other causes of hypersomnia.

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 under the influence of 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 an environment conducive to sleep. MWT should not be performed while the patient is under the influence of 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:

- Excessive daytime sleepiness 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 (PSG) since the onset of symptoms, 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

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- 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:

- Excessive daytime sleepiness has been present for at least 8 weeks
- The patient has at least **ONE** of the following:
    - Difficult morning awakening
    - Prolonged sleep during primary sleep period
    - Sleep drunkenness
    - Frequent non-refreshing daytime naps
    - The patient has undergone PSG or HSAT and symptoms persist despite adequate treatment of obstructive sleep apnea (if present)

References

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. Maski KP, Amos LB, Carter JC, et al. Recommended protocols for the Multiple Sleep Latency Test and Maintenance of Wakefulness Test in children: guidance from the American Academy of Sleep Medicine. Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine. 2023
5. 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.

Codes

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

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SLEEP DISORDER TREATMENT MANAGEMENT

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

General Information

Guideline Scope

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.

Clinical Indications

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

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

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Treatment with CPAP is considered medically necessary for a patient aged 18 years or older 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
- Appropriate CPAP level has been determined

Treatment with CPAP is considered medically necessary for a patient aged 17 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 for a patient aged 18 years or older 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
- The patient has no contraindication to the use of APAP (see *APAP contraindications*)

Treatment with APAP is considered medically necessary for a patient aged 17 years or younger when ALL of the following criteria are met:

- A lab-based sleep study demonstrating AHI of at least 1 (one)
- It is the opinion of the treating provider that APAP is preferable to CPAP for this individual
- **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

Ongoing treatment with APAP or CPAP

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:

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- Use of the PAP device for at least 4 hours per night on 70% of nights during a consecutive 30-day period within the preceding 90 days
- The treating provider (as distinct from the DME provider) attests that the patient is accruing clinical benefit from PAP therapy at current usage levels

*Demonstration of compliance is not required for non-adult patients.

Contraindications

Contraindications to APAP

- 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 opiate use
- Use of supplemental oxygen for 24 hours daily
- 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 **ANY** of the following:
    - Increase in arterial $PaCO_2$ (or surrogate measure) to a value exceeding 55 mmHg for at least 10 minutes
    - Greater than 10 mmHg increase in arterial $PaCO_2$ (or surrogate measure) during sleep (compared to an awake supine value) to a value exceeding 50 mmHg for at least 10 minutes
    - Sleep oximetry demonstrates oxygen saturation ≤ 88% for ≥ 5 consecutive minutes of nocturnal recording time (minimum recording time of 2 hours), recorded while breathing the patient's prescribed FiO_2

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.
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.

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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. Chang JL, Goldberg AN, Alt JA, et al. International consensus statement on obstructive sleep apnea. International forum of allergy & rhinology. 2022.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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.

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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.

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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

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A7045	Replacement Exhalation Port for PAP Therapy
A7046	Water chamber for humidifier, replacement, each

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Bi-Level Positive Airway Pressure Devices

General Information

Guideline Scope

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.

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 for at least 6 weeks

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- 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
- The treating provider (as distinct from the DME provider) attests that the patient is accruing clinical benefit from PAP therapy at current usage levels

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

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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.
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.
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.
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.
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.
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.
5. Ozsancak A, D'Ambrosio C, Hill NS. Nocturnal noninvasive ventilation. Chest. 2008;133(5):1275-1286.

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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.

Codes

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.

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CPT/HCPCS

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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
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

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Management of Obstructive Sleep Apnea using Oral Appliances

General Information

Guideline Scope

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. Oral appliances should be used with caution when there is comorbid temporomandibular joint disease and should be avoided in patients with periodontal disease.

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 to prevent dislodging the device

Clinical Indications

Custom Fabricated Oral Appliances (HCPCS 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 ALL of the following criteria are met:

- The appliance is a TRD or a Medicare-compliant MRA
- The patient does not have periodontal disease or temporomandibular joint dysfunction

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- **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
- The patient does not have periodontal disease
- **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 (HCPCS 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.

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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.
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.
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).
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.

Codes

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D9947	Custom sleep apnea appliance fabrication and placement
D9948	Adjustment of custom sleep apnea appliance
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

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K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
0964T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; single arch, without mandibular advancement mechanism
0965T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, not-fixed hinge mechanism
0966T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, fixed hinge mechanism

Management of Obstructive Sleep Apnea using Implanted Hypoglossal Nerve Stimulators

General Information

Guideline Scope

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

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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 13 and 21 years
- AHI or RDI between 10 and 50 with less than 25% central apneas after prior adenotonsillectomy (or contraindications thereto)
- 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. Ishman SL, Maturo S, Schwartz S, et al. Expert Consensus Statement: Management of Pediatric Persistent Obstructive Sleep Apnea After Adenotonsillectomy. Otolaryngol Head Neck Surg. 2023;168(2):115-30.
6. 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.
7. 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.
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.

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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.
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.
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.
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.
31. Zhu Z, Hofauer B, Wirth M, et al. Selective upper airway stimulation in older patients. Respir Med. 2018;140:77-81.

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Codes

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64568	Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator [when specified as a hypoglossal nerve stimulator (e.g., Inspire V single lead HNS)]
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), non-rechargeable [when specified as a component of HNS]
C1778	Lead, neurostimulator (implantable) [when specified as a component of HNS]
C1787	Patient programmer, neurostimulator [when specified as a component of HNS]
L8680	Implantable neurostimulator electrode, each [when specified as a component of HNS]
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only [when specified as a component of HNS]
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension [when specified as a component of HNS]

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Miscellaneous Devices in the Management of Obstructive Sleep Apnea and Restless Legs Syndrome

General Information

Guideline Scope

This guideline addresses two approaches to the management of obstructive sleep apnea: electronic positional therapy and neuromuscular electrical training of the tongue musculature. In addition, the guideline addresses the use of peroneal nerve stimulation for treatment of restless legs syndrome.

Overview

The severity of OSA varies with position, and in some patients the frequency of apneic and hypopneic events are markedly reduced by avoidance of the supine sleeping position. Electronic devices which prompt the patient to avoid sleeping supine have been proposed as a treatment for mild and moderate OSA. Such devices have been tested against conventional treatments (positive airway pressure therapy and oral appliances). Although the devices reduce AHI, trials have been limited by number of participants and duration of follow-up. Currently there is no high-quality evidence supporting the use of electronic positional therapy for management of OSA.

Because OSA is related in part to laxity of the musculature of the tongue and upper airway muscles, awake training of these muscles to improve sleeping airway patency has been proposed as an approach to treatment. However, in small trials, exercise training targeting the tongue and upper airway muscles has not been shown to be beneficial in treatment of OSA. An electronic removable intraoral device, providing intermittent neuromuscular training of tongue musculature was approved by FDA in 2021. Several small trials have assessed the efficacy of this device in management of snoring and mild OSA. The trials, which are mostly industry-sponsored, are limited by size, duration of follow up, and absence of a control group. To date, no high-quality evidence of benefit has been provided for neuromuscular electrical training as a treatment for OSA.

Restless legs syndrome (RLS) is a poorly understood sleep-related disorder in which patients report an urge to move their legs during periods of immobility. The symptoms occur predominantly in the evening or at night and are relieved by movement. Although the pathophysiological mechanisms are not clearly defined, iron deficiency and pregnancy are associated. Treatment consists of avoidance of exacerbating factors, pharmacological intervention (gabapentin enacarbil, gabapentin, pregabalin, extended-release oxycodone), and iron supplementation. Recently, bilateral high-frequency peroneal nerve stimulation has been proposed as a treatment option for patients with refractory RLS. To date, studies supporting this therapy have been small, mostly industry sponsored, and non-blinded (making interpretation of subjective endpoints challenging).

Exclusions

Electronic positional therapy is considered **not medically necessary** in all clinical scenarios.

Neuromuscular electrical training of the tongue musculature is considered **not medically necessary** in all clinical scenarios.

Peroneal nerve stimulation for management of RLS is considered not medically necessary in all clinical scenarios.

References

Specialty Society Guidelines and Systematic Reviews

1. Rueda JR, Mugueta-Aguinaga I, Vilaró J, et al. Myofunctional therapy (oropharyngeal exercises) for obstructive sleep apnoea. Cochrane Database Syst Rev. 2020;11(11):Cd013449.

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2. Srijithesh PR, Aghoram R, Goel A, et al. Positional therapy for obstructive sleep apnoea. Cochrane Database Syst Rev. 2019;5(5):Cd010990.
3. Winkelman JW, Berkowski JA, DelRosso LM, et al. Treatment of restless legs syndrome and periodic limb movement disorder: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2024.

Other Literature

1. Baptista PM, Martínez Ruiz de Apodaca P, Carrasco M, et al. Daytime Neuromuscular Electrical Therapy of Tongue Muscles in Improving Snoring in Individuals with Primary Snoring and Mild Obstructive Sleep Apnea. J Clin Med. 2021;10(9).
2. Benoist L, de Ruiter M, de Lange J, et al. A randomized, controlled trial of positional therapy versus oral appliance therapy for position-dependent sleep apnea. Sleep Med. 2017;34:109-17.
3. Berry RB, Uhles ML, Abaluck BK, et al. NightBalance Sleep Position Treatment Device Versus Auto-Adjusting Positive Airway Pressure for Treatment of Positional Obstructive Sleep Apnea. J Clin Sleep Med. 2019;15(7):947-56.
4. Bogan RK, Roy A, Kram J, et al. Efficacy and safety of tonic motor activation (TOMAC) for medication-refractory restless legs syndrome: a randomized clinical trial. Sleep. 2023;46(10).
5. Buchfuhrer MJ, Baker FC, Singh H, et al. Noninvasive neuromodulation reduces symptoms of restless legs syndrome. J Clin Sleep Med. 2021;17(8):1685-94.
6. Buchfuhrer MJ, Roy A, Rodriguez S, et al. Adjunctive tonic motor activation enables opioid reduction for refractory restless legs syndrome: a prospective, open-label, single-arm clinical trial. BMC neurol. 2023;23(1):415.
7. Charlesworth JD, Adlou B, Singh H, et al. Bilateral high-frequency noninvasive peroneal nerve stimulation evokes tonic leg muscle activation for sleep-compatible reduction of restless legs syndrome symptoms. J Clin Sleep Med. 2023;19(7):1199-209.
8. de Ruiter MHT, Benoist LBL, de Vries N, et al. Durability of treatment effects of the Sleep Position Trainer versus oral appliance therapy in positional OSA: 12-month follow-up of a randomized controlled trial. Sleep Breath. 2018;22(2):441-50.
9. Kotecha B, Wong PY, Zhang H, et al. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. Sleep Breath. 2021;25(4):2083-90.
10. Mok Y, Tan A, Hsu PP, et al. Comparing treatment effects of a convenient vibratory positional device to CPAP in positional OSA: a crossover randomised controlled trial. Thorax. 2020;75(4):331-7.
11. Nokes B, Baptista PM, Martínez Ruiz de Apodaca P, et al. Transoral awake state neuromuscular electrical stimulation therapy for mild obstructive sleep apnea. Sleep Breath. 2023;27(2):527-34.
12. Roy A, Ojile J, Kram J, et al. Long-term efficacy and safety of tonic motor activation for treatment of medication-refractory restless legs syndrome: A 24-Week Open-Label Extension Study. Sleep. 2023;46(10).
13. Rozeman AD, Ottolini T, Grootendorst DC, et al. Effect of sensory stimuli on restless legs syndrome: a randomized crossover study. J Clin Sleep Med. 2014;10(8):893-6.
14. Şanli ZS, Ortaç EA, Binokay H, et al. Transcutaneous electrical nerve stimulation in the management of restless legs syndrome symptoms: A single-blind, parallel-group clinical study. J Sleep Res. 2024;33(5):e14167.
15. Singh H, Baker FC, Ojile J, et al. Efficacy and safety of TOMAC for treatment of medication-naïve and medication-refractory restless legs syndrome: A randomized clinical trial and meta-analysis. Sleep Med. 2024;122:141-8.
16. Wessolleck E, Bernd E, Dockter S, et al. Intraoral electrical muscle stimulation in the treatment of snoring. Somnologie (Berl). 2018;22(Suppl 2):47-52.

Codes

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A4544	Electrode for external lower extremity nerve stimulator for restless legs syndrome
E0490	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0491	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply

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E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
E0743	External lower extremity nerve stimulator for restless legs syndrome, each

History

Status	Review Date	Effective Date	Action
Revised	01/30/2025	11/15/2025	Independent Multispecialty Physician Panel (IMPP) review. Inclusion of alternate devices for HSAT; expansion of criteria for when etiology is unclear; clarifications for CSA and PLMD; age change to clarify non-adults; removed extraneous criteria to determine CPAP level; removed age restriction from APAP contraindications; clarified that clinical benefit attestation must come from the treating provider; clarification to avoid use of oral appliance for patients with periodontal disease or TMJ dysfunction; addition of restless legs syndrome criteria. Added references. Added HCPCS codes A4544 and E0743.
Updated codes 07/01/2025	n/a	Unchanged	Added CPT codes 0964T, 0965T, 0966T, and 64568.
Updated coded 04/01/2025	n/a	Unchanged	Added HCPCS code L8688 to hypoglossal nerve stimulators section.
Revised	04/15/2024, 01/23/2024	10/20/2024	IMPP review. Changed “hypersomnolence” to “excessive daytime sleepiness”; expanded definition of obesity hypoventilation syndrome to include sleep oximetry criteria; new polysomnography indication added prior to implantation of a hypoglossal nerve stimulator; new home sleep apnea testing indication added prior to hypoglossal nerve stimulator; new contraindication added to APAP titration in which the use of supplemental oxygen for 24 hours daily is specified; age range for the hypoglossal nerve stimulator for those with Down Syndrome was changed to ages 13-21; clarified that the sleep diagnostic testing required before MSLT/MWT must be PSG and removed reference to HSAT; exclusions added for miscellaneous devices. Added final section and references. Added required language per new Medicare regulations. Added HCPCS codes C1778, C1787, E0490, E0491, E0492, E0493, E0530, L8680, L8681.
Revised	01/24/2023	09/10/2023	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 CDT codes D9947 and D9948.

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Status	Review Date	Effective Date	Action
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.

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